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ABSTRACT

An integrated and multidisciplinary undergraduate core curriculum (COMCORE) was developed and implemented between 1992 and 1995 at the University of Massachusetts Lowell's College of Management. Traditional business core courses were replaced with a year-long integrated program, which simulated a new-product development process, and consisted of nine credit-hours each in the fall and spring semesters. Program objectives were to provide knowledge (at a level comparable to junior-year business students) of methodologies associated with business functional areas and to integrate this knowledge by requiring student teams to apply concepts to a practical business problem or process that cuts across functional areas. Additional objectives were to enhance student writing and oral presentation skills, expose students to electronic communications, and encourage team-building skills. While comparisons with a national sample of business school students showed comparable functional area knowledge was acquired by students in both groups, students in COMCORE developed a more integrated view of business processes and acquired better general business skills than those in traditional programs. Extensive appendices include: core curriculum assessment questions, a questionnaire of core competencies, case materials, and a writing style guide. (SW)

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Cover Sheet

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College of Management
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ENHANCING BUSINESS EDUCATION USING AN INTEGRATED CORE CURRICULUM

The College of Management at the University of Massachusetts Lowell developed and offered an integrated multidisciplinary undergraduate core curriculum between Fall 1992 and Spring 1995. This program used the new product development process as an integrative vehicle replacing six stand-alone business core courses. Student teams planned the development of a new product and its introduction to the global market. Comparisons with a national sample of business school students showed that functional area knowledge acquired by students in both groups was comparable, yet students in the experimental program developed a more integrated view of business processes and acquired better general business skills than those in more traditional programs.

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ENHANCING BUSINESS EDUCATION USING AN INTEGRATED CORE CURRICULUM

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ENHANCING BUSINESS EDUCATION USING AN INTEGRATED CORE CURRICULUM

EXECUTIVE SUMMARY

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PROJECT OVERVIEW

The integrated core curriculum project at the College of Management started on September 1, 1992. The first year of the project concentrated on curriculum development; the second and the third years were for implementation of the curriculum. During this three-year effort, two interdisciplinary cases were prepared and used to develop an integrated approach.

This project represented a "paradigm shift" in which six traditional core courses in the College's business curriculum were replaced with a year-long integrated program of nine credit-hours each in the Fall and the Spring semesters. The program was structured around the new product development process.

PURPOSE

The traditional business curriculum is designed to produce functional specialists, with little emphasis on integration among functional areas. At most schools, the business core consists of a number of different courses, each dealing with a different functional area. This approach does not agree with the contemporary management practice in the business world where major processes frequently cut across traditional functional boundaries.

Using the new product development process, the program integrated the theory and practice of functional areas in a cohesive framework while ensuring that students develop an understanding of fundamental concepts and methodologies underlying each of the functional disciplines. In addition, the program sought to strengthen the students' writing and oral presentation skills to build and improve their self esteem, and to lay a foundation for a successful career.

BACKGROUND AND ORIGINS

In both domestic and foreign markets, American businesses face intense competition from foreign companies. These agile competitors rapidly bring quality new products to market. Key differences exist in how technology is managed in the U.S. compared to its strongest global competitors, who often achieve higher productivity.

Foreign competitors often work closely with other industrial partners (e.g. suppliers) and effectively integrate people from different functional areas in the design and manufacture of new products. In traditional U.S. firms, emphasis was placed on developing specialists who may suffer from segmented thinking. To alleviate this problem, progressive U.S. companies now do utilize cross-functional teams to improve productivity in the critical area of new product development.

This program was developed to provide students with broader vision and a better understanding of integration across functional areas in order to improve productivity and thus enhance competitiveness of their employers.

PROJECT DESCRIPTION

In this program, student teams were required to respond to the needs of decision-makers evaluating the introduction of a new product in two industries – static discharge control and orthopedic implant. Over the two cycles of the project, student teams were assigned specific new products in these industries. Each cycle was offered over an academic year. Students in the program enrolled in nine credit-hours in each of the two semesters in lieu of six traditional courses: Business Finance, Management Information Systems, Marketing Management, Operations Management, Organizational Behavior, and Business, Society, and Public Policy – six required courses in the College's core curriculum.

Student teams prepared "deliverables" requiring them to evaluate a product as it progressed in a company from a concept through commercialization in world-wide markets. In preparing these reports, students had to develop product characteristics needed for market success, prepare marketing plans, evaluate manufacturing alternatives, generate financial projections, analyze distribution alternatives, and develop organizational capabilities needed to support the product. Thus, techniques and methodologies of various functional areas had to be applied to an ongoing project, and interdependencies among these functions had to be considered. This approach provided a holistic view of how a firm manages a critical process, in this instance new product introduction, and tended to break down functional silos resulting from a poor understanding of relationships among these functional areas.

EVALUATION/PROJECT RESULTS

Two fundamental issues needed to be considered in evaluating the program: 1) Did the students develop an adequate understanding of the techniques and methodologies of the functional areas included in the program? 2) Did they develop an adequate understanding of how these functional areas relate to each other in a realistic decision-making context?

To address the first question, students in this program were compared to a national sample. This sample was obtained via the Core Curriculum Assessment Program (CCAP) of the American Assembly of Collegiate Schools of Business. Sample questions for each of the six areas integrated were administered to students in the program. Their performance was compared to that of the national sample in the CCAP database. Analysis of this data showed that there were no statistically significant differences in the understanding of the fundamental concepts of the six functional areas between students in this program and those in the CCAP sample.

Two strategies were used to develop feedback about the second question. Assessment information was obtained through focus discussion groups conducted by an outside evaluator, and a questionnaire was developed and administered to students in two Senior year courses in the College in which both students who had completed this program and others who had completed the traditional core curriculum were enrolled. Information from this questionnaire was analyzed by group. The two groups were students who completed this program and students who completed the traditional core curriculum. The evaluation of information gathered from these sources indicated that the integrated program indeed did help students to develop a more holistic understanding of business processes, and concomitant improvement of self-image in spite of the fact that the two groups had the same mean grade point averages.

Thus, assessment activities indicated that the program was successful on both major criteria established for the project.

Nevertheless, several issues must be considered in future integrative efforts. Students constantly compare demands imposed on them by such programs to those on students in the traditional program. This can be a significant source of student stress because the program required additional integrative activities such as group deliverables which are not part of the traditional courses. Including materials from all six areas in the first deliverable further exacerbated this problem. Integration also requires significant faculty time. New materials have to be developed and tested. Course materials and classroom coverage must be coordinated among faculty members in the program. Functional area materials need to be reorganized to address the requirements of decision issues incorporated in the deliverables. In order to actualize a cohesive program, course policies need to be coordinated and some grading activities need to be completed as a consensus among various faculty members in the program. This is particularly the case for integrative student projects such as the deliverables required in this program. Academic approval and administrative flexibility may have to be negotiated. These activities require substantial effort and time and can become sources of frustration for both the faculty and the students. As a matter of fact, due to workload concerns during the first year of implementation, the College's curriculum committee approved awarding of three additional credits to students in this program. The small enrollment in the second year of the program's implementation may have been due to some of these concerns.

In this program, the outside evaluator – a faculty member from the College of Education specializing in curriculum development and assessment – played a significant role by frequently meeting with student and faculty groups to identify these concerns before they became significant problems. Since information became available quickly and disputed issues were handled expeditiously, the program progressed satisfactorily. Without an impartial outside facilitator who was not teaching in the program, small issues could have mushroomed into significant problems. Therefore, the role of such a counsel cannot be overemphasized in programs focusing on significant paradigm shift.

SUMMARY AND CONCLUSIONS

This project demonstrated that integrative programs can be very effective. In spite of the significant effort required of both students and participating faculty, the ultimate goal was achieved – students participating in the program received a better education.

Faculty learned that integration is a major challenge. It must not be viewed as simply revising a course or set of courses. Significant effort will be required. Unanticipated difficulties may emerge. Therefore, faculty planning such effort must recognize that adjustments may have to be made during implementation, and must undertake this activity in a learning spirit with willingness to continue making adjustments. But, in the end, the reward will come from recognizing that these students are better prepared to join the work force.

ENHANCING BUSINESS EDUCATION USING AN INTEGRATED CORE CURRICULUM

PROJECT OVERVIEW

The integrated business core curriculum project at the College of Management (COM) started on September 1, 1992 under a grant funded by the U.S. Department of Education's Fund for the Improvement of Postsecondary Education (FIPSE). The first year of this three-year project was for curriculum development activities. The second and the third years implemented the new curriculum using two slightly different approaches and two separate year-long cases.

A new approach was utilized in this curriculum development effort. The traditional business school core curriculum consists of separate functional area courses, and an attempt is made in the end to integrate these functional areas, typically using a series of cases. The approach in this program was unique in that core concepts normally taught in separate functional area courses were taught in the context of a major business process. The major business processes around which the core curriculum was based were new product development and management of an ongoing product. The project was given the name COMCORE (representing College Of Management business CORE curriculum).

Existing products were used as the basis for the structure of classroom instruction and related student activities. The historical development of these products was traced by contacting business managers involved in the actual development of the products. The knowledge gained from their experiences was incorporated into two product cases – called "School Cases." These cases were used as a basis for teaching different functional areas, demonstrating linkages among them, and highlighting their role in major business processes. The overall learning objective was to help students develop a more holistic framework for understanding and applying functional area knowledge in business administration.

PURPOSE

Due to intense foreign competition, industry has been forced to reevaluate its business practices, productivity, and competitive position. Many companies have moved to break down functional silos and have adopted cross-functional teams to manage major processes. In contrast, most academic business programs have remained function oriented. COMCORE is designed to break down traditional organizational boundaries and encourage students to develop skills necessary for establishing and maintaining cooperative working relationships with others. Rather than taking a semester each of Marketing Management, Business Finance, Operations Management, Organizational Behavior, Management Information Systems (MIS), and Business, Society, and Public Policy (BSPP) emphasis is placed on all of these subjects concurrently by including them as part of an all-inclusive project focusing on the product development process. This contributes to a better educated and more productive manager, consistent with current practices in industry.

PROGRAM GOALS

The COMCORE program was designed to help students understand practical business problems, and learn functional area methodologies and the team process needed for their successful resolution. This led to the formation of two specific program goals:

- Provide knowledge of methodologies and techniques associated with traditional business functional areas at a level comparable to business undergraduate junior-year students at an accredited university; and
- Integrate this knowledge of functional areas in a cohesive framework by requiring student groups to apply these concepts to a practical business problem or process that cuts across these functional areas.

In addition to these major program goals, additional sub-goals were developed. These included strengthening students' communications capabilities by enhancing their writing and oral presentation skills, introducing students to the world of electronic communications, and encouraging team-building skills. These sub-goals do not enhance a student's technical skills, but build and improve their self-esteem and lay the foundation for a successful career.

PROGRAM OBJECTIVES

Goals identified above were operationalized through a series of objectives to be accomplished for each semester of the year-long program. Major objectives for the two semesters were:

First Semester

- Acquaint students with "real world" business problems, e.g. new product development;
- Introduce key decision issues relevant to these problems;
- Demonstrate and analyze different techniques and alternative approaches to the solution of these complex tasks; and
- Examine the effect of foreign competitive practices, the impact of ethical issues, and create conceptual frameworks necessary to address these issues.

Second Semester

- Examine the creation of a support organization for the new product;
- Introduce impact of local business practices, impact of infrastructure, and other variants;
- Understand the concept of quality in the context of a service organization; and
- Examine approaches toward the recognition of change driven by internal and external forces.

Following sections describe the COMCORE methodology for accomplishing these goals and actual attainment of these goals as determined by assessment of student achievements.

BACKGROUND AND ORIGINS

Competitive problems faced by American companies in global markets have been under substantive discussion over the past two decades. American companies not only faced stiff competition in foreign markets, but also saw their domestic dominance slowly erode in the favor of more agile foreign corporations. This has forced American industry to reevaluate its business practices and search for new ways to enhance productivity and improve competitive positions.

Paradoxically, the U.S. is also credited with offering the best opportunities for management education. A survey[1] in the early nineties reported that "America, it is said, has the best business schools, Japan the best businesses." Other studies explored this question from different perspectives. Studies by the Graduate Management Admission Council [1990] and Porter and McKibben [1988] also recommended a closer link to practical management issues, above and beyond theoretical model building, to make management education more relevant. Linder and Smith [1992] highlighted the complex issues in reorienting management education. In several instances, the results of theoretical academic research projects have significantly altered accepted practice in many industries.[2] Muller, Porter, and Rehder [1991] asserted that discontent with a university-based management degree has led to close links among businesses and academia in Europe. Students of these European business programs generally work on real problems faced by the companies sponsoring either the student or the program.

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[1] A global survey by The Economist [1991] highlighted some of the issues that were driving changes in graduate management education in the U.S. Significant discussion was devoted to the need for the

The traditional undergraduate curriculum in business has been focused on functional area specialization with minimal emphasis on the operational integration which must take place among the several business functions. Anderson [1992] described a study by the American Assembly of Collegiate Schools of Business (AACSB) suggesting that the two principal deficiencies of contemporary business education are curricula which place insufficient emphasis on generating vision in students and the lack of integration across functional areas.

Many schools have revised their graduate management programs to address some of these concerns. Changes in undergraduate programs, however, are not as widespread. This program therefore focused on developing and evaluating an integrative approach at the undergraduate level to provide students with a broader vision than provided by a traditional functional-based program.

University of Massachusetts at Lowell is part of the state-funded university system. It is one of the five campuses in the state and offers one of the two AACSB accredited business programs among four such programs. The College of Management at Lowell enrolls about 1,000 undergraduate students and about 250 graduate students. Situated about 25 miles north of Boston, this campus competes with a large number of private academic institutions in close proximity which also offer AACSB accredited undergraduate and graduate business programs. The Lowell campus does not offer a doctoral degrees in management related fields.

The College of Management was visited for AACSB reaccreditation during the implementation of this project. Therefore, significant administrative flexibility was needed to allow this project to proceed further. Appropriate faculty committees approved implementation of the experimental project. Open meetings and presentations at regularly scheduled College faculty meetings, kept all faculty members informed about the project's progress. College administration and COMCORE faculty had to be flexible in terms of teaching loads. For example, some faculty members teaching during the first semester of the implementation of the project received teaching credit during the following semester. This administrative flexibility was easily obtained during the first year of classroom implementation. During the second year, program changes did not require this flexibility.

The College made significant resources available for the project. Teaching assistants, equipment, and special office space was allocated to COMCORE. These items were critical

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development of theoretical models to enhance understanding of operations of a business versus the educational goal of management education to develop managers who have enough practical understanding to lead companies through turbulent, changing nature of the global markets.

[2] See, for example, the debate in "MBA: Is the Traditional Model Doomed?" following the Linder and Smith [1992] article.

factors in the success of the project. The program also received high praise from the AACSB reaccreditation visitation team which specifically mentioned COMCORE as an evidence of the College's ability to design and implement high-quality programs.

Changes in College administration during the project caused some problems in the third year (which was the second year of classroom implementation). The dean of the College resigned and two interim deans took over the administrative responsibilities who were not fully familiar with the scope and rationale of COMCORE. This had a direct impact on the class size for the second year. Based on some advice, almost half the students initially enrolled in the program changed over to the traditional program. The second year therefore had a small class size. However, it allowed COMCORE faculty to improve communications with students and take a more proactive role in assisting students due to reduced time demands caused by fewer students.

The program also received significant support from the business community. This support was in the form of personnel time for factory visits and information for cases, samples, literature, promotional materials, reports, and other similar materials essential to develop a real-life context for students in the program. Two executives-in-residence also provided significant support and assistance. They helped faculty with industry information and contacts, wrote letters to and discussed the benefits of an integrated approach with potential students, assisted placement efforts by writing letters of support to potential employers for students who completed the program, and made themselves available to students to provide career guidance.

PROJECT DESCRIPTION

COMCORE faculty utilized standard published text books, developed special case materials, and collected industry information to help students develop a comprehensive knowledge of the new product development process. Major faculty activities included developing integrative cases, reorienting functional area curricula to address the needs of managers at various steps of the selected new product development process, designing student deliverables to help integrate functional areas, delivering the revised curriculum, and assessing and disseminating information.

THE INTEGRATIVE CASE

The integrative case for the first year was in the static control industry. It was designed around a fictitious company called CSI, Inc., a manufacturer and marketer of static electricity protection devices for the electronics industry. The integrative case for the second year was OrthoKinesis, Inc., a fictitious surgical products company, producing and marketing orthopedic implant devices.

In the CSI, Inc. case, an executive of the company sees a market for dissipating static electricity generated by normal human movements and friction in the electronics manufacturing industry. Accidental static electricity discharge during handling materials can permanently weaken the complex integrated-circuit chips used in many electronics applications. Thus, the concept for a new product line is born. The company develops this new business through a division called StatBusters. StatBusters will develop, produce, and market products designed to control and eliminate static electricity at various stages of the electronics goods manufacturing process.

Student groups were required to develop plans for introducing new products in the general area of control of static electricity in the electronics industry. Each group was responsible for a specific product in the static protection industry. The four products selected for student deliverables were ionizer fan, tote box, wrist strap, and test kit – each product performing a specific role in an integrated solution to static discharge problem. In order to develop the background information for these products, and to provide students with a library of information in this industry, a survey was conducted during the summer of 1993. Using this telephone survey, product literature, product samples, and a variety of other materials were collected. These materials were made available to students in the COMCORE office staffed by a teaching assistant.

The OrthoKinesis case – developed over the second year for use during the third year of the project – was built around a small, fictitious company producing highly specialized finger and elbow joint implant devices. This company is portrayed as a respected, high-quality producer in a small, niche market. Concerned with the cost-containment frenzy in the healthcare industry, OrthoKinesis fears that price competition for its small volume products may force it to merge with a large implant manufacturer. In order to protect itself, OrthoKinesis decides to expand its product line by introducing new products for hip and knee implants which offer large, world-wide markets with several established manufacturers. The challenge is to develop new product lines for hip and knee implant devices in a cost-effective and timely manner. In addition, it must capture markets for these products by capitalizing on its reputation as a producer of finger and elbow implants, and building on its relationships with orthopedic surgeons performing implant procedures. In accomplishing this transformation from a niche market to a competitive market, OrthoKinesis must conform to all regulatory requirements for producers of implant devices.

Student groups were required to develop plans to refocus the company on the development of hip and knee implant devices. They were expected to focus on foreign markets where the competition is not as keen as in the U.S. The physical characteristics of the population in their chosen country of initial focus had design implications for the implant devices. During the first semester of delivery, each group worked on only one product line, that is, hip or knee implant products. During the second semester, both products had to be included in their plans. Once again, background data for this industry, product literature, and a library of information for students was collected by contacting actual companies competing in this industry. Industry observers from the securities industry, trade associations, and publishers specializing in orthopedic industry were also contacted for information to develop the case. The COMCORE faculty group visited a manufacturer of implant devices during case write-up, and revisited this design and manufacturing facility with students during the first semester. Thus, both faculty and students had access to a major competitor for hip and knee implant devices.

STUDENT DELIVERABLES

Integrative student reports – called deliverables – were used to help students understand the impact of one area on other functions of a business. Starting from a simple understanding of issues relating to each separate area, deliverables increased in complexity as the year progressed.

The first deliverable focused on concept development issues of new product introduction. The student groups simulated new product development teams in business firms. They were required to justify to senior management the addition of their product as a profitable venture. Specifically, the student groups justified the addition of their product, and identified the managerial, financial, and manufacturing implications of this product addition.

In the next deliverable, students addressed the issues of resource availability, product design, technical specifications, and financial feasibility of the new product line. At this point, a case update was added. This update comprised of the production and financial information needed to correctly address the questions posed in the deliverable. The information was compiled through actual industry research discussed above, and was another segment of COMCORE that allowed students to combine their functional knowledge with real world information.

Additional deliverables added considerations of risk and market uncertainty, supplier requirements, and specific customer requirements. Student groups prepared sales forecasts, a marketing plan for their product, and implementation proposals. They were required to identify impact on manufacturing, and estimate budgetary needs to commercialize their products.

In addition to the written portion of the deliverables, the students were also evaluated on the oral presentation of these materials to faculty groups. The six COMCORE faculty members were divided into three groups of two, each group responsible for a specified number of student groups throughout the semester. These faculty "mentor" groups were responsible for any questions or problems encountered by the student groups under their supervision.

EVALUATION/PROJECT RESULTS

The assessment of the project responded to both formative and summative information needs. Formative evaluation activities were developed to support decision making regarding the case-related curriculum materials designed during the development phases and to assess the students' reactions to the instructional process in this effort. Other activities assessed the understanding of management concepts by students exposed to the new curriculum in comparison to those from traditionally taught classes.

During the first two project years, there were frequent data collection and evaluation activities. This was necessary due to the desires of the COMCORE faculty to continue to improve the process by continuous feedback, and to assure that objective and effective assessment followed their efforts. Due to better understanding of the student/process issues, a significantly smaller COMCORE student group, and the need for the evaluator to focus on assessing the outcomes of the first-year delivery effort, less intensity was needed during the third project year.

In the planning phase over the first year, the evaluator met frequently with the faculty development group, observing their process and achievement. The faculty met weekly for almost twelve months, occasionally meeting as small teams to work out a particular aspect of the integration of content. The evaluator's role was primarily that of observer, noting the unfolding of new collaborative relationships first, sharing of information across disciplines, and then gradually increasing awareness of how to link and then inter-weave the courses through conceptual development and applications. During the second project year, the faculty implemented the curriculum for the first time. The evaluator continued to attend project faculty meetings and added evaluation of classroom and other implementation activities such as deliverables. Since half the faculty group involved in the third year was also in the first group, there was less need to interact with the curriculum planning process. Therefore, most of the evaluation activities during this year involved meeting with students and assessing the effectiveness of the previous year.

SUMMATIVE EVALUATION OF INSTRUCTIONAL IMPACT

The COMCORE project integrated six core areas in business to prepare students to develop both a knowledge base and to foster the integration of knowledge needed to successfully apply their learning to business practice. The first major goal of the project was to "Provide knowledge of methodologies and techniques associated with traditional business functional areas at a level comparable to business undergraduate junior-year students at an accredited university." To meet this goal, the evaluation plan provided for a comparison of COMCORE student performance with that of a national sample of business students. The selected vehicle for the comparison was the Core Curriculum Assessment Program (CCAP) database of the AACSB.

While the CCAP items do not reflect integration of content in the manner attempted by the COMCORE program, they provide feedback on acquisition of the knowledge base accepted as necessary by professionals in business management programs. Ten CCAP items were selected for each of the six content areas integrated into the COMCORE curriculum: Business Finance, Marketing Management, MIS, Operations Management, Organizational Behavior, and BSPP. COMCORE teaching faculty did not have access to the results of administration of various questions to samples within CCAP. This eliminated any difficulty bias resulting from selecting questions based on how other groups performed in answering them.

Sample

All students were notified that evaluation items would be included in the examinations at the end of the Spring semester. (Due to the small second year group, more non-standard testing such as computer assignments was used. Therefore these students could not be included in this sample). Consistent with federal guidelines for the treatment of human subjects, students were also informed that participation in the evaluation would be voluntary and that the items would not be included in the computation of the grades.

Methodology

The faculty group met weekly throughout the academic year. During these meetings the faculty selected items from the database that reflected their course goals. The evaluator requested that they choose items that did not need modification, and the faculty complied. The selected items for each area are presented in the format in which students completed them in Appendix A.

The administration of the items was handled by faculty during three final examination periods at the end of the year of experience with COMCORE. This provided as natural a setting as possible in which to judge student performance. The items covering Organizational Behavior and BSPP were presented at the end of the final examination for these areas, and 35 forms were scored for each of the two areas. The items for Business Finance, MIS, Marketing Management, and Operations Management were presented in a separate examination, and 36 students returned machine-readable answer sheets.

Scoring was completed with a tally of students selecting incorrect responses. The incorrect response tallies were transformed into the number and percent of COMCORE students responding correctly. The CCAP information used in the comparison was the percent of the people answering correctly, defined as P-VALUE in the database. COMCORE faculty members did not know these P-VALUES while selecting the questions for their area. P-VALUE information was missing in the CCAP database for three of the sixty questions selected by the COMCORE faculty. In the following tables, these items are left blank in the CCAP column.

Student's t-test was used to test the null hypothesis that the two samples (COMCORE students and those that answered the questions in the CCAP database) are drawn from the same population. Thus, the alternate hypothesis is that there are differences in the performance of

COMCORE students and those who took CCAP examinations. A significance level of five percent corresponding to a t-test probability of .05 was considered desirable to reject the null hypothesis. Rejecting the null hypothesis implies that the performance of the two groups was different. Accepting the null hypothesis implies that the groups performed at the same level. Therefore, if in a functional area the null hypothesis could not be rejected, this would indicate that based on the questions included in the test, COMCORE students achieved comprehension level not different from that of their counterparts in the national sample. A t-test of significant mean differences was conducted on the results aggregated across items for each functional area.

Results

The results that follow below are reported by academic content area. Each table reports the number and percent of correct responses for COMCORE students and percent of people who answered the item correctly in the CCAP sample. The last row of each table indicates the probability associated with the Student's t-test for these correct responses.

Marketing Management

In the area of Marketing Management, the results suggest that COMCORE students performed at the level of the national samples of students (See Table 1). The overall average number of items correct for the national sample was 61.9 while that for COMCORE students was 64.7. Only 3 items involved differences of more than 10 percent. Only items 4 and 7 showed substantial differences in correct responses of COMCORE students versus the national sample. Scoring for item 2 in this part of the examination was revised by CCAP developers. All alternatives were considered correct, resulting in the 100% correct response rate for this item.

The null hypothesis could not be rejected at the .05 level due to a t-test probability of 0.8233. Therefore, COMCORE students' understanding of marketing issues is not different from that of those in the CCAP samples.

Management Information Systems (MIS)

The MIS faculty member in COMCORE disagreed with CCAP correct answer for one question used for comparison. Therefore, as shown in Appendix A, correct choice for COMCORE students was different from that suggested in the CCAP database.

The results for the ten MIS items (See Table 2) suggest that COMCORE students performed slightly above, but within 10 percent of, the national samples of students. The overall average percentage of students getting these items correct for the national sample was 64.3 while the COMCORE average was 68.9. On specific items, however, some differences were more than 10 percent. On items 1, 2, 4, 5, 7 and 8, COMCORE students out-performed the national sample while on the remaining items the national sample percentages were higher.

Given the t-test probability of 0.5772, the null hypothesis could not be rejected at the .05 level. This suggests that COMCORE students had comprehension of issues relating to management information systems not significantly different from students in the CCAP sample.

Table 1

Comparison of COMCORE and CCAP Results

Marketing Management

QUESTION NUMBER	COMCORE		CCAP CORRECT PERCENT
	CORRECT RESPONSES	PERCENT CORRECT	
1	30	83.3	87.3
2	36	100.0	100.0
3	21	58.3	61.3
4	17	47.2	15.0
5	13	36.1	22.7
6	28	77.8	81.4
7	24	66.7	86.0
8	24	66.7	68.1
9	30	83.3	
10	10	27.8	35.6
Average	23.3	64.72	61.93
Student's t-test probability for COMCORE vs. CCAP percent correct: 0.8233			

Table 2

Comparison of COMCORE and CCAP Results

Management Information Systems

QUESTION NUMBER	COMCORE		CCAP CORRECT PERCENT
	CORRECT RESPONSES	PERCENT CORRECT	
1	33	91.7	76.2
2	29	80.6	48.5
3	11	30.6	45.0
4	22	61.1	49.9
5	27	75.0	70.9
6	14	38.9	61.0
7	30	83.3	73.6
8	27	75.0	56.4
9	24	66.7	69.0
10	31	86.1	93.3
Average	24.8	68.9	64.38
Student's t-test probability for COMCORE vs. CCAP percent correct: 0.5772			

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Operations Management

Results suggest that for the ten Operations Management items, COMCORE students performed in a manner comparable to the national samples (See Table 3). The average number of students getting items correct for the national sample was 56.4, while the COMCORE average was 52.5. While on most items COMCORE students performance was consistent with the national sample, on items 2, 3, and 7 the national sample percentages were substantially higher. Scoring on item 9 was revised by the CCAP developers. All responses were correct; hence the 100% figure.

As in the previous areas, the t-test probability of 0.7654 implies that the null hypothesis is not rejected at the .05 level. Therefore, COMCORE students understand operations management issues to a degree that is statistically consistent with those who took the CCAP examinations.

Table 3

Comparison of COMCORE and CCAP Results

Operations Management

QUESTION NUMBER	COMCORE		CCAP CORRECT PERCENT
	CORRECT RESPONSES	PERCENT CORRECT	
1	10	27.8	29.6
2	21	58.3	73.1
3	2	5.6	24.1
4	11	30.6	39.4
5	29	80.6	88.9
6	10	27.8	40.6
7	14	38.9	56.1
8	31	86.1	79.1
9	36	100.0	100.0
10	25	69.4	33.5
Average	18.9	52.51	56.44
Student's t-test probability for COMCORE vs. CCAP percent correct: 0.7654			

Organizational Behavior

For Organizational Behavior area, the results for the ten items (See Table 4) suggest that COMCORE students performed above the national samples. The average number of students getting items correct for the national sample was 52.2 while the COMCORE average was 64.2. On 4 items (1, 2, 6, and 10) COMCORE students performed substantially above the national sample.

The t-test probability was 0.1592. Therefore, the null hypothesis could not be rejected at the .05 level. However, the average for COMCORE students was higher than that for the national sample by more than ten percent, and the t-statistic was smallest of all areas. Accepting the null hypothesis suggests that understanding of organizational issues in the two groups was not different.

Table 4
Comparison of COMCORE and CCAP Results
Organizational Behavior

QUESTION NUMBER	COMCORE		CCAP CORRECT PERCENT
	CORRECT RESPONSES	PERCENT CORRECT	
1	33	93.3	22.3
2	32	91.4	80.7
3	27	77.1	67.8
4	14	40.0	47.1
5	17	48.6	50.8
6	17	48.6	31.1
7	22	62.9	54.7
8	19	54.3	58.1
9	17	48.6	46.3
10	27	77.1	63.5
Average	22.5	64.19	52.24
Student's t-test probability for COMCORE vs. CCAP percent correct: 0.1592			

Business Finance

The results for Business Finance suggest that the COMCORE students performed within the 10 percentage points of national samples (See Table 5). The average number of students getting items correct in the national sample was 41.4, and the COMCORE group average was 31.9. On 7 out of the 10 items (See items 1, 3, 4, 5, 6, 7, and 8) COMCORE students performed rather consistently with the national sample. On the remaining three items, the national sample percentages were higher by more than 10 percent. Timing and concomitant retention issues discussed later in this section played a part in the results shown here.

However, the t-test probability of 0.2688 indicates that the null hypothesis was confirmed (that is, it could not be rejected). Therefore, COMCORE students achieved a comprehension of finance methodology which is statistically not different from the national sample.

Business, Society, and Public Policy (BSPP)

On the ten BSPP items also the COMCORE students performed within the range of national samples (See Table 6). Compared to 61.7 for COMCORE, the average number of items correct for the national sample was 67.75. On specific items some discrepancies were more than 10%. On items 8 and 9, COMCORE students out-performed the national sample while on items 1, 2, 4 the national sample percentages were higher. Lack of a comparable course in the national sample, and some other issues discussed later affected the observed results in this area.

The t-test probability of 0.4988 implies that the null hypothesis could not be rejected at the .05 level. Therefore, comprehension of fundamental concepts in this area is not different in the COMCORE and the CCAP test groups.

Table 5

Comparison of COMCORE and CCAP Results

Business Finance

QUESTION NUMBER	COMCORE		CCAP CORRECT PERCENT
	CORRECT RESPONSES	PERCENT CORRECT	
1	13	36.1	37.5
2	6	16.7	62.3
3	5	13.9	21.7
4	21	58.3	48.9
5	21	58.3	57.3
6	9	25.0	30.0
7	7	19.4	26.2
8	20	55.6	65.8
9	2	5.6	16.4
10	11	30.6	48.1
Average	11.5	31.95	41.42
Student's t-test probability for COMCORE vs. CCAP percent correct: 0.2688			

Table 6

Comparison of COMCORE and CCAP Results

Business Society and Public Policy

QUESTION NUMBER	COMCORE		CCAP CORRECT PERCENT
	CORRECT RESPONSES	PERCENT CORRECT	
1	24	68.5	80.0
2	25	71.4	88.0
3	17	48.6	43.9
4	10	28.6	43.6
5	23	65.7	74.0
6	29	82.9	82.7
7	18	51.4	
8	20	57.1	49.8
9	32	91.4	80.0
10	18	51.4	
Average	21.6	61.7	67.75
Student's t-test probability for COMCORE vs. CCAP percent correct: 0.4988			

Summary of National Comparisons and Discussion

This evaluation provided information about areas of strength and weakness in student acquisition of the knowledge base for business majors. The results suggested that for the first implementation year, the COMCORE students were successful in acquiring information at a level not inconsistent with national samples. In all six areas integrated into COMCORE, the null hypothesis could not be rejected, implying that in terms of acquired knowledge of subject matter included in a typical business core curriculum, there is no statistically significant difference between the COMCORE students and the CCAP national sample. Based on averages, COMCORE students equaled or out-performed national samples in Marketing, Organizational Behavior, MIS, and Operations Management. In the areas of Business Finance and BSPP these students lagged national samples.

Although none of these differences was statistically significant, several circumstances explain the disparities of average performance of COMCORE students with the CCAP data where this average is lower for COMCORE students. Both BSPP and Business Finance areas were primarily included in the Fall semester, resulting in a considerable time lag (five and one-half months) between instruction and testing at the end of the Spring semester. Both these areas include somewhat technical materials. Finance is highly quantitative in nature, and BSPP includes materials relating to specific legal issues. Generally, the longer the time lapse between the learning and subsequent use of technical materials, the higher is the retention loss. The CCAP tests, on the other hand, were conducted immediately after instruction in the same semester. Thus students in the CCAP samples did not suffer from retention problems associated with the subject matter of technical areas. Due to its public policy focus, the BSPP course is also different from courses included in CCAP, thus making comparisons somewhat difficult. In addition, the faculty member representing BSPP was forced by health considerations to take an extended leave from the campus, creating another disadvantage for COMCORE students. Finally, the COMCORE curriculum stressed application of integrated information rather than recall of discrete facts. Major assignments stressed group work, simulating an actual business environment, not traditional concept acquisition emphasized in CCAP. In light of these issues, we are satisfied with student performance in these areas. Indeed, no student has complained that COMCORE did not prepare them adequately for Senior year work.

FORMATIVE EVALUATION OF THE INSTRUCTIONAL PROCESS

The second major program goal was to "Integrate this knowledge of functional areas in a cohesive framework by requiring student groups to apply these concepts to a practical business problem or process that cuts across these functional areas." Due to the significantly different nature of the COMCORE program, other models are not available nationally to facilitate comparisons to understand accomplishment of this goal. The focus of the assessment effort in this area was on the curricular process and comparison to other COM students.

In order to assess the curriculum and the instructional process from this perspective and to obtain feedback about the several sub-goals of the project, focus discussion groups, observations of classroom events, and a survey questionnaire were employed. Three focus groups were held, two during the first year and one during the second. Observations included both classes in which faculty presented information and led discussions, and in which student groups presented their work on case-related deliverables. The questionnaire – designed with the help of a faculty member in the area of marketing research – was used to compare COMCORE students to others in the College of Management who had completed their core curriculum in the traditional program. The outside evaluator also attended several meetings of the COMCORE faculty.

Focus Group Observations

The first focus group and classroom observations in the Fall, 1993 term suggested both strengths and weaknesses in the first implementation of the integrated curriculum. While students valued the application of concepts, they reported that changes were needed to improve their understandings of grading policies, to modify the due dates of assignments in order to accommodate both examinations and deliverable assignments, and to increase communication with the faculty. A second focus group after the midterm of the Spring, 1994, semester, revealed that the students saw improvements in the grading policy, workload distribution and in the lead time prior to due dates for deliverables. The students assessed themselves as learning a great deal about applying management concepts to how an actual business operates and about developing presentations, and they appreciated enhancements to the Stat-Busters, Inc. case write-up. Areas needing continued consideration included communication with some faculty and enhancement of integration through deliberate, consistently implemented, connections among courses. Students also asked that the faculty build in more computer applications. The observations of classroom process underscored the value of integrating courses; for example, the evaluator observed the enthusiasm of students as two faculty engaged in dialogue with each other and with students about how each discipline related to an aspect of the Stat-Busters, Inc. case.

During the second year, the focus discussion and observations revealed that the smaller group of students were quite aware of the integrated nature of the COMCORE experience and of the usefulness of the case in demonstrating applications of the principles of management. The workload issues were largely resolved, and the case , as the focus of curriculum integration, seemed to function better than in the first year. The classroom process and communication with faculty were a strength of the second year.

Questionnaire Discussion and Analysis

A brief questionnaire (Appendix B) was designed to compare students who had taken the traditional core courses in the College to those who had enrolled in the COMCORE program. The questionnaire was administered in two classes which required completion of all core courses to enroll. In order to minimize any bias, the last question asked which core program was completed by the student. A total of 103 responses were received, of which 34 were COMCORE students, and the remaining 69 students had completed the traditional core curriculum. The questionnaire queried student reactions to several aspects of their experience in, and opinions about the impact of, the core courses. The 11 attitude items focused on reactions about the student's (a) preparation for senior level concentration courses, (b) understanding issues related to application, (c) affective responses to preparation for applying content in the workplace, and (d) ability to work on a team. A five-point, Thurstone-type scale allowed students to select a degree to which s/he agreed with, or disagreed with, the statement in a given item.

The number of respondents and the number of responses falling into each category is reported by group in Table 7. Means and standard deviations are given in Table 8 as descriptive indicators of overall group response. Table 8 also reports the nonparametric Mann-Whitney U test of differences across the reactions of COMCORE and traditionally taught COM students.

Table 7
CORE ASSESSMENT SURVEY
Summary of Responses

No.	Question	Response Group	Total	Strongly Disagree				Strongly Agree
1.	My core courses have prepared me for senior level courses in my area of concentration.	COMCORE	33	0	1	5	12	15
		Other COM	69	0	6	17	35	11
2.	These courses have improved my basic understanding of how business functions such as finance, manufacturing, and marketing "fit together".	COMCORE	32	1	0	6	12	13
		Other COM	69	1	3	25	33	7
3.	I believe that I have a good understanding of how different departments of a business organization cooperate in managing products.	COMCORE	32	0	1	7	12	12
		Other COM	69	1	1	23	34	10
4.	I am confident that I will be able to make a valuable contribution to my employer's business upon graduation from the BSBA program at UML.	COMCORE	32	0	0	2	18	12
		Other COM	69	0	4	19	23	23
5.	I understand the basic issues involved in introducing industrial product in a foreign market.	COMCORE	32	0	1	7	14	10
		Other COM	69	4	10	23	24	8
6.	I believe that my core experience made me a more confident speaker before groups of business executives.	COMCORE	31	0	0	1	8	22
		Other COM	68	9	13	22	19	5
7.	After completing the core program, I have a good understanding of what must be included in a professional business report.	COMCORE	32	1	1	4	12	14
		Other COM	68	4	19	21	20	4
8.	As a result of my experience in the core courses, I have developed a more professional writing style.	COMCORE	31	0	0	4	20	7
		Other COM	68	8	8	24	22	6
9.	My core courses provided experience to make me a more effective member of a team.	COMCORE	31	0	0	2	15	14
		Other COM	68	2	6	22	23	15
10.	I understand how groups of people work together to complete a joint assignment.	COMCORE	31	0	0	2	12	17
		Other COM	69	1	5	17	22	24
11.	The core program increased my interest in international business issues.	COMCORE	31	0	3	9	15	4
		Other COM	66	5	9	20	22	10
12.	Give your best estimate of your GPA at the end of this term.	COMCORE	32					
		Other COM	64					

The overall reactions to their core curriculum were generally favorable in both groups. Across all items and both groups, the means ranged from 3.01 (essentially neutral) to 4.68 (highly favorable). Neither group displayed an overall negative view on any single item. The dispersion of the responses was, however, greater for traditionally taught COM students on nine of the 11 items. While this may be an artifact of the numbers of students in each sub-sample (a much larger traditionally taught student group), the data are quite consistent across items.

Due to ordinal data and because the frequencies, especially in the COMCORE group, are not normally distributed, a nonparametric test was used to determine statistically significant differences across the groups. Only two items failed to show significant differences on the Mann-Whitney U test when an alpha of $p < .05$ was chosen. On the other nine items the responses of the two groups were sufficiently different to allow rejection of the null hypothesis.

The items on which both the COMCORE and traditionally taught COM students agreed were Items 4 and 11. These items deal with affective responses to the student's experience. Item 4 queries the confidence of the student about making a valuable contribution to an employer's business after graduating. The mean response of COMCORE students was 4.31; and that of traditionally taught COM students was 3.94 ($p = .069$); both groups expressed a favorable view of their potential contribution. On Item 11, students in both groups asserted neutral to positive views that the core had increased their interest in international business issues (See Table 8).

On all remaining items, across the four issues embedded in the items, the COMCORE students responded in a significantly more positive way than did traditionally taught students. The null hypotheses were rejected for all nine items and in every case the mean score for COMCORE students was more favorable than that for the traditionally taught COM students.

COMCORE students echoed a higher degree of agreement that their core courses had prepared them for the senior level courses in their concentrations. This response further strengthens and validates the findings reported in the previous section on CCAP comparisons. Mean response by COMCORE students was 4.22 ($\sigma = .82$) versus 3.74 ($\sigma = .83$) by other COM students. By the time of this survey, COMCORE students were competing with those from the traditional program in advanced courses. If they had felt disadvantaged in preparation needed to perform well in Senior level courses, their response would not have been significantly higher than those of the other students in these courses. This is particularly significant because the two groups had the same grade point average, with COMCORE students showing wider distribution than those from the traditional program (See Item 12 in Table 8).

COMCORE students expressed greater agreement with having acquired intellectual skills and content relevant to business practice than did traditionally taught students (See Items 2, 3, 5, 7, and 8.). They also rather strongly agreed that they understood how people work together to complete a joint assignment and that they had learned to become a more effective member of a team through the COMCORE program (See Items 9 and 10.). COMCORE responses to teamwork items were significantly more positive than traditionally taught COM students.

On one item that dealt with an affective issue, COMCORE students were more positive in their ratings than other students. Item 6 focused on confidence as a speaker before groups of business executives, and COMCORE students gave this item their highest rating (Mean = 4.68), and had the least variation among themselves ($\sigma = 0.53$) across all items for both groups of students. These results were consistent with focus discussion group results in which students reported the importance to them of learning to give the deliverable presentations.

IMPLICATIONS FOR INTEGRATION OF MANAGEMENT CURRICULA

During the two years of instruction, several issues had to be dealt with in implementing the COMCORE program. These issues were not necessarily the same for both years. Yet, they have several implications for the integration of management curriculum. This section discusses these implications and other insights learned as a result of various evaluation activities.

Table 8
CORE ASSESSMENT SURVEY
Analysis of Responses

Q. No.	Response Group	Total	Mean	Std. Dev. σ	Mann-Whitney U Test Probability	Hypothesis of No Difference at 5% level
1.	COMCORE	33	4.22	0.82	.0068	Reject
	Other COM	69	3.74	0.83		
2.	COMCORE	32	4.13	0.93	.0022	Reject
	Other COM	69	3.61	0.78		
3.	COMCORE	32	4.09	0.84	.0387	Reject
	Other COM	69	3.74	0.77		
4.	COMCORE	32	4.31	0.58	.0690	Accept
	Other COM	69	3.94	0.91		
5.	COMCORE	32	4.03	0.81	.0014	Reject
	Other COM	69	3.32	1.04		
6.	COMCORE	31	4.68	0.53	.0000	Reject
	Other COM	69	2.97	1.14		
7.	COMCORE	32	4.16	0.97	.0000	Reject
	Other COM	68	3.01	1.02		
8.	COMCORE	31	4.1	0.59	.0000	Reject
	Other COM	68	3.15	1.11		
9.	COMCORE	31	4.39	0.61	.0003	Reject
	Other COM	68	3.63	1.01		
10.	COMCORE	31	4.48	0.62	.0077	Reject
	Other COM	69	3.91	1		
11.	COMCORE	31	3.63	0.84	.2553	Accept
	Other COM	66	3.35	1.12		
12.	COMCORE	32	2.9	0.66		
	Other COM	64	2.89	0.42		

During the first, and most difficult implementation year, the faculty were developing the second semester activities and assignments while implementing the first semester of the program. The focus discussion groups conducted during the first year of COMCORE classes suggested a number of changes that would be helpful to the experience of the students. At the time of the first focus group, the faculty had already begun to make some changes as they sensed needs for change themselves. Other implementation issues continued to need attention for the whole first year. During the second year, the smaller size of the COMCORE student group and shifts in faculty configuration resulted in an improved instructional process, but a few concerns remained. The following sections summarize issues and concerns about the two years of COMCORE classes.

Instructional Issues and Concerns from COMCORE A

Impact on learning of students

The faculty were urged to maximize the sense of integration and application of content by providing more opportunities for students to raise questions to which two or more faculty, representing various disciplines, could respond. Such interdisciplinary discussions took place rarely in the first year, but faculty had to learn to sense good opportunities for such discussion after years of teaching a single discipline.

Other formats of interaction across disciplines were suggested in which faculty and students could participate. For example, the small groups could present a deliverable or some aspect of it, and faculty from two disciplines might comment on the strengths and weaknesses or make suggestions. Again, faculty could react to an issues or a deliverable presentation by posing dilemmas to be resolved with different input from each discipline. Again, one faculty person can propose a strategy based on maximizing his/her interest; students of a small group might, with a second faculty person as consultant, create a rebuttal or compromise strategy.

The results of a comparison of COMCORE with a traditionally taught national sample of students suggested that the COMCORE students were very successful in acquiring conceptual information at a level consistent with national samples. In all content areas discussed earlier, the students equaled, or out-performed, national samples on items drawn from standardized multiple choice examinations. The implication is that concept acquisition does not suffer when coursework is integrated across a number of disciplines.

Likewise, in a comparison of attitudinal responses of COMCORE and traditionally taught COM students at the University of Massachusetts Lowell, COMCORE students were more favorable in their judgments of learning at statistically significant levels. They expressed confidence in their learning with respect to application in a business setting, preparation for senior level courses in their concentrations, and understanding of international business issues.

Small group project assignment

Faculty were urged to use small group activities to move students gradually towards the skills necessary to prepare the deliverables and to develop other possibilities for small group interactions during class time.

Workload for students

At the time of the focus discussion data collection, the faculty had already made more information available about deliverables and had structured the remaining work to provide more lead time to students. The students remained concerned about how heavy the workload seemed in contrast to other courses. They said they were responsible for the text (similar to other classes) and the application activities that required extensive out of class time with their groups (beyond the requirements of traditional core courses).

The recommendation was also made to avoid the double scheduling of quizzes or tests. The students cited examples of two examinations on one day and a deliverable due date within a few days of the examinations. The students had not planned their work far enough ahead to accommodate all three. Many students commented that the 20+ hours of outside employment in addition to full course loads also made the workload very difficult to handle. Due to serious workload concerns, three additional credits were approved for COMCORE.

The Stat-Busters, Inc. case

The case seemed to be functioning rather well, and faculty were seen, by student focus groups, as increasing their use of the case in classes. Evaluation based recommendations suggested that as they continued to revise and enhance the case, the faculty should consider the suggestion of students that the case should model the structure desired in the deliverables.

Grading policy

When integrating courses the faculty need to consider well in advance of the first examination how the grading will be done, who will do it, and how the grade will contribute to each course for which credit is given. Because faculty were learning as they went along, some revisions in the grading policy produced frustration and uncertainty in the students. In this integrated curriculum, COMCORE students signed up for individual courses as did other COM students. In a well established integrated curriculum, one would assume that the college would approve special six or nine hour courses and allow those courses to fill traditional degree requirements.

Feedback to Faculty

The students appreciated the one-minute feedback and other frequent evaluations. These allowed them to communicate with the faculty and the principal investigator. Formal evaluations provided only limited opportunities to communicate for students who were all too well aware that they were part of an "experimental" program. The caution was added, however, that faculty, as groups and as individuals, must be flexible enough to change in light of the feedback.

Student Perception of Faculty

Although students did not understand, the faculty had accepted the stress involved in an attempt to revise curriculum and implement change simultaneously. In addition, the faculty relinquished independent control to that by a teaching team. Several consequences occur in the instructional process, and communication with students is a challenge to walk the line between asking students to be overly tolerant without information and expecting students to accept virtually any inconvenience or insecurity because faculty were under stress.

For example, students found difficult accepting a faculty member's uncertainty about answering a questions because it affected other COMCORE faculty. Although faculty provided immediate feedback on issues of course content related to their area, this was the case concerning "housekeeping and logistical" items where a common understanding of policy was essential to maintain program cohesiveness.

Given these conditions, the COMCORE faculty needed to be careful so as not to communicate their personal stress to students. The faculty group had to consider ways to revise its own working style to ease some of the tension. To help students develop a better understanding of issues faculty was struggling with, a student representative was asked to join the faculty during their weekly meetings. This helped students better understand why some questions could not be answered immediately by one faculty member.

Recognition of Accomplishment

The faculty needed to clearly recognize that there was substantial progress in integrating the curriculum and in implementing it. The issues raised in this evaluation suggested need for changes to enhance effectiveness but did not call into question the value of what had been accomplished.

Perception of changes by COMCORE A students

The focused discussion that took place about mid-way through the Spring semester gave students an opportunity to review their experiences and consider strengths and weaknesses in the COMCORE process and curriculum.

The COMCORE students clearly assessed themselves as learning a great deal about applying management concepts to how an actual business operates and about developing presentations. They also noted improvements in the workload distribution, scheduling of examinations and quizzes, and in the lead time prior to due dates for deliverables. Areas needing continued consideration included communication with faculty, degree of integration of courses, and the dynamics of the classroom. Students made two concrete suggestions: focusing on the entire product line from the beginning of the COMCORE year and building in more computer applications.

The grading policy continued to be of concern to students. They felt that some of the COMCORE A schemes for assigning grades across faculty and across course credits were overly convoluted, and doubted that they could be consistently applied. Allowing a student representative to sit through faculty deliberations of the grading process helped address the issue.

Students continued to resent some interactions with one faculty member who they considered "difficult." This raises the issue of the type of faculty characteristics that facilitate integrated curricula.

Evaluation data suggested a need for a more integrated style of classroom presentation. Because faculty members were concerned about covering the subject matter of their functional area, students found the faculty less integrated than students were expected to be! The data resulted in a number of recommendations about classroom process:

1. Team teaching could allow the faculty to create more possibilities for class participation by students and thus provide a needed change of pace from a lecture/discussion format.
2. Following the suggestion made by students to include computer applications, the evaluation report suggested that use of e-mail and computer laboratory time might be an avenue to partnerships across courses of record and to breaking up long class periods with activity-based learning experiences.

The COMCORE Spirit

A new issue arose during the latter part of the COMCORE A year. The students had begun to develop a sense of confidence about what they were learning and about doing presentations. They might have been ready to see themselves as special because of their connection to COMCORE, rather than as simply working harder than the traditionally taught COM students. The evaluation report suggested that faculty may want to consider means to enhance the group spirit, particularly since recruitment for the second year was somewhat related to the attitude of the first year students.

Instructional Issues and Concerns from COMCORE B

The second group of COMCORE students had a distinctly different experience because the size of the group was small, allowing more individual contact with faculty. The following topics are similar to those above and reveal the greater ease of the faculty in integrating the courses, allaying student concerns and developing a second case for application of concepts.

Impact on Learning by Students

The students clearly assessed themselves as learning a great deal about applying management concepts to how an actual business operates and about developing presentations. This group of students was aware of the integrated nature of the COMCORE experience and of the usefulness of the case in demonstrating applications of the principles of management. At this point, the project did not appear to need change related to the level of application activities. The new case required fine tuning, but most students seemed to find the application of concepts to be helpful.

Workload

Consistent with the hope of the evaluation reports of the first year, the workload issues had been largely resolved. Although students continued to report uncertainty about presentations which are new to them, their concerns about the scheduling of examinations and deliverable presentations were far more moderate than those of the previous COMCORE group.

The OrthoKinesis, Inc. Case

The new case developed for the second year functioned better than the one in the first year. Due to the first-year experience of the half of the COMCORE faculty, the group was better versed in the development process and that had contributed to smoother construction and implementation.

Student Perception of Faculty

The classroom process and communication with faculty was a strength of the second year. The size of the student group was very small in comparison to the first COMCORE year, but this issue, which was so important in the first year, was handled well during the second year. Change in the faculty group and change in the course content contributed to a much smoother year. The continuation of three faculty gave the new faculty group enough consistency and experience that many pitfalls in communication with students were avoided.

New Concerns in COMCORE B

Students cited concerns with administrative issues at the college level. They were unclear about how COMCORE scheduling might preclude taking other required courses, and they were concerned about the following year in meeting requirements via the COMCORE credits. Although these concerns were largely unfounded, the evaluation data underscored the need for faculty and administrations to clarify issues of scheduling and meeting graduation requirements, both for themselves and for students, well in advance of commencement of integrated programs.

Future Plans

The COMCORE experiment was endorsed by the College of Management faculty to develop an understanding of the impact of an integrated program on various constituencies on the campus. Therefore, in this regard the first step is to provide COM faculty with the feedback necessary for evaluation by providing copies of this report to the entire faculty. Lessons learned from this project suggest that COMCORE can be most useful for students with high levels of motivation who have already had some exposure to management issues. During the academic year, proposals will be developed and discussed in College of Management's Undergraduate Academic Policy Committee to institutionalize COMCORE as an honors programs for a small group of students. One of the benefits of the small group during the second year of instruction was that faculty were able to reject some student assignments. It required student groups to meet with faculty in groups and rewrite the deliverable until it was satisfactory. Thus, the small student group allowed faculty to shift focus away from evaluation to continuous improvement until all students were able to perform at a high level. This approach will work well with a small group of dedicated students in an honors program who are motivated by a challenge to perform consistently at a high level. We feel this will provide the most benefit for students.

Summary

In summary, there are several instructional issues to consider for integrated curricula. With respect to learning by students, the data supports the integrated curriculum based on concept acquisition in comparison to standardized test data on national samples and based on student perception of changes in themselves. The students may need several months of coursework and, perhaps a semester grading period, to gain confidence in their learning, but they do acquire that confidence by the end of their experience.

In developing integrated curricula, faculty may need to give extra consideration to workload and scheduling issues. Separate examinations for each discipline area may be ill received, particularly if integrated assignments are also given. Realistically, several semesters may be needed to work out a reasonable schedule of assignments that ensure both concept acquisition and integration of content application. The development and use of a case greatly enhances the application, but also adds another set of content and relationships to be learned by students.

Policy at the college level and within the program needs to be reviewed carefully by faculty since students entering an integrated program for the first time will be insecure about how the program will affect their grade point averages and graduation requirements. Of immediate concern to students is the grading policy for assignments and courses, who will grade them, how consistently the criteria are applied, and so on. Endorsement of the integrated program by the university administration is essential to clearing the way for policy changes necessary to keeping students moving easily towards graduation.

The student perception of faculty is affected greatly by the classroom dynamics and how much faculty integrate their own instructional presentations. Students need a model of integrated thinking and classroom activity.

The stress on faculty will be clear in integrated programs. Care must be exercised to avoid communicating that stress to students. The faculty group may need to monitor itself and learn to help each other across some stressful moments in the semester. Choice of faculty for an integrated curriculum should be limited to those who have experience in, and willingness to join, collaborative endeavors.

Finally, the faculty need to be occasionally reminded of the great challenge they have undertaken. The process is unlike traditional university instruction and requires change in commitments, perspectives on one's work life, new learning of content in other disciplines, and rethinking the scope and sequence of one's own discipline. The task is not trivial, such as simply revising a course or syllabus. The faculty who implement such an integrated curriculum must accept problems in the first year and recognize the need to continue making adjustments during the second and subsequent years. Finally, the faculty need to know that they have been successful, particularly because based on measures of both concept acquisition and attitudinal judgments their students have been successful.

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APPENDIX A

CORE CURRICULUM ASSESSMENT PROGRAM

Questions Used by Area

Each item is reproduced by functional area. An asterisk (*) denotes the correct answer. Summary statistics for each area are presented following listing of the questions.

QUESTIONS FOR BUSINESS, SOCIETY, AND PUBLIC POLICY

1. Who selects the chief executive in the majority of publicly owned corporations?

   (A) Stockholders
   * (B) A board of directors
   (C) A personnel officer
   (D) A selection committee

2. Which of the following activities is an example of socially responsible corporate philanthropy?

   (A) Sponsorship of the arts
   (B) Gifts to charities and universities
   (C) Executive loan programs to service organizations
   * (D) All of the above

3. When compared to the traditional economic model, the social responsibility model places more emphasis on:

   (A) Profits for shareholders
   * (B) Responsiveness to stakeholders
   (C) The importance of competition
   (D) Adherence to government regulation

4. Which of the following statements does [NOT] apply to public policy formulation?

   (A) The branches of government are involved in policy formulation under a system of checks and balances.
   * (B) The public interest and the public good are easily determined factors shaping public policy.
   (C) Policy formulation decisions are often the result of interest group bargaining efforts.
   (D) Possible international reactions to policy decisions are prime considerations in policy formulation.

5. Which of the following functions is [NOT] a major role of government in its relationship with business?

   (A) Prescribing rules by which business is conducted
   * (B) Selling goods to businesses
   (C) Promoting & subsidizing businesses
   (D) Protecting society against business exploitation

6. In attempting to match individual workers to jobs, managers should consider all of the following characteristics [EXCEPT]:

   * (A) race, sex, and age
   (B) knowledge, skills, and abilities
   (C) motivational orientations and needs satisfaction
   (D) attitudes and beliefs

7. Which of the following actions should an organization take to compensate employees according to the comparable worth standard?

(A) Price jobs strictly according to external labor market rates.
(B) Classify jobs according to their relative contribution to organizational effectiveness, but price them according to external labor market rates.
* (C) Classify and price jobs according to their relative contributions to organizational effectiveness.
(D) Classify jobs into a few broad categories and differentiate compensation within categories on the basis of seniority.

8. Which of the following situations is an apparent conflict between Title VII of the Civil Rights Act and affirmative action ?

(A) Segregation
(B) Aptitude tests
* (C) Reverse discrimination
(D) Bona fide occupational qualifications

9. All of the following activities are currently advocated by the consumerism movement [EXCEPT]:

(A) disclosing more product information
(B) designing more safety features into products
* (C) placing fewer restrictions on the manufacturers of consumer products
(D) protecting the environment for the consumer

10. Which of the following is the major argument for the deregulation of industry?

(A) it results in higher prices
* (B) it encourages competition
(C) it reduces trade barriers
(D) it shrinks the size of the government

Summary of Business, Society, and Public Policy Questions

SUMMARY ITEM	N	PERCENT
Number of Students	35	100.0
Average Number of Correct Responses/Question	21.6	
Average Percent of Students Answering a Question Correctly		61.7
Average Number of Correct Answers/Student	6.2	62.0

QUESTIONS FOR BUSINESS FINANCE

1. [Ignore tax effects. From which interest table was the figure .91511 probably taken if it came from the row marked by three periods and a column marked 3%?

* (A) Present value of $1
(B) Present value of an annuity of $1
(C) Future amount of $1
(D) Future amount of an annuity of $1

2. [Income Statement]

Revenues	$1000
Operating expenses	400
Interest expense	200
Depreciation	100
Tax rate	40%

Based on the information shown above, what is the cash flow after taxes and interest?

(A) $ 80
(B) 180
(C) 240
* (D) 280

3. A firm sells an average of $20,000 per month on open account. If it increases its accounts receivable annual turnover from 4 to 6, what reduction will occur in the average level of accounts receivable?

* (A) $ 20,000
(B) $ 30,000
(C) $ 40,000
(D) $ 60,000

4. The initial cash outlay for a new computer is $50,000. If a firm has a 10% cost of capital, what is the minimum annual cash flow that would give a positive net present value for the purchase of the computer?

(A) $ 5,000
(B) $ 45,000
(C) $500,000
* (D) Cannot be determined from the given information

5. Apex Company manufactures a product that has a sales price of $54 per unit. Total fixed costs are $9,000 per month and variable costs are $18 per unit. To make a profit in June of $1,800 how many units must Apex sell?

* (A) 300
(B) 180
(C) 150
(D) 90

6. If an account pays 10%, how much must be deposited to withdraw $1,000 per year forever, beginning in two years?

(A) $ 8,264.46
* (B) $ 9,090.91
(C) $ 10,000.00
(D) $ 11,000.00.

7. A company has earnings before interest and taxes of $1,000,000 and has a corporate income tax rate of 40%. The only interest-bearing debt the company has outstanding is a $5,000,000 long-term bank loan at 8%. How many times is interest earned before taxes?

(A) 0.9
(B) 1.5
(C) 1.9
* (D) 2.5

8. A change in the firm's break-even point would [NOT] be caused by a change in the firm's:

(A) variable cost per unit
* (B) corporate tax rate
(C) price per unit
(D) fixed costs

9. Which of the following events will decrease an investment's future annual net cash flows for capital budgeting?

(A) A decrease in the firm's marginal income tax rate
(B) A decrease in the investment's annual fixed costs
(C) An increase in the investment's annual interest expense
* (D) A decrease in the investment's annual depreciation expense for taxes.

10. Based on the actual structure of dividend payout rates across firms, which of the following types of firms will usually have the highest dividend payout ratio?

(A) Fast-growing firms with high-return investment opportunities
* (B) Mature firms with a relatively stable earnings stream
(C) Firms that are closely held by investors in high tax brackets
(D) Firms that have a history of unstable earnings

Summary of Finance Questions

SUMMARY ITEM	N	PERCENT
Number of Students	36	100.0
Average Number of Correct Responses/Question	11.5	
Average Percent of Students Answering a Question Correctly		31.9
Average Number of Correct Answers/Student	3.2	32.0

QUESTIONS FOR MANAGEMENT INFORMATION SYSTEMS

1. How is the data in a computerized business information system organized?

(A) By bytes, bits, nibbles, and lines
(B) By lists, trees, sequences, and structures
(C) By sequential and random structures
* (D) By fields, records, and files

2. Which of the following systems is [BEST] suited for assisting a marketing manager in deciding whether to introduce a new product in a new location?

(A) A database management system
* (B) A decision support system
(C) An electronic data-processing system
(D) A management information system

3. Which of the following statements [BEST} explains the rise in popularity of such input devices as point-of-sale terminals that permit data to be captured at the data-generating event?

(A) They are less expensive than other input devices.
(B) They impress the customer or user.
* (C) They reduce the potential for errors.
(D) They permit faster batch processing.

4. Which of the following definitions [BEST] describes an operating system?

(A) A set of application programs
* (B) A set of programs used to allocate the computer system's resources
(C) A set of programs written by high-level managers
(D) A set of utility programs

5. Text, graphics, or preprinted documents can be transmitted to a remote location by:

(A) an optical character reader
* (B) a facsimile device
(C) a microfiche reader
(D) a shared-logic word processor

6. Compared to an upper-level manager, a lower level manager would have a greater need for:

* (A) real-time information
(B) recurring historical reports
X (C) external information
(D) random access to information

7. The primary objective of a decision support system is to:

(A) provide backup for a manager once a decision has been made
(B) make decisions for a manager
* (C) improve the effectiveness of decision making
(D) help a manager to justify a particular action after it has been taken

8. Which of the following amounts of computer memory storage is equal to 64,000 bytes?

(A) 64 megabytes
(B) 64 gigabytes
* (C) 64 kilobytes
(D) 64,000 kilobytes

9. Which of the following business applications is [BEST] suited for batch processing?

(A) Airline reservations
* (B) Payrolls
(C) Hotel reservations
(D) Hospital medical treatment systems

10. Computers are useful for which of the following tasks?

(A) Speeding up the processing of transactions
(B) Amassing large quantities of data
(C) Improving accuracy and reliability in data processing
* (D) All of the above tasks

Summary of Management Information Systems Questions

SUMMARY ITEM	N	PERCENT
Number of Students	36	100.0
Average Number of Correct Responses/Question	24.8	
Average Percent of Students Answering a Question Correctly		68.9
Average Number of Correct Answers/Student	6.9	69.0

QUESTIONS FOR MARKETING MANAGEMENT

1. Which of the following statements about the marketing role of cultural and social trends is true?

(A) Marketing managers should attempt to control cultural and social trends.
(B) Marketing managers should not be concerned about cultural and social trends.
* (C) Marketing mix decisions generally follow cultural and social trends rather than lead them.
(D) Cultural and social trends have little impact on consumer buying behavior.

2. One disadvantage of using a licensing arrangement to manufacture a product in a foreign country is that:

(A) the licensing firm then cannot establish its own sales branches to market the product in that foreign country.
(B) a large investment by the licensing firm is required
(C) the licensing firm then cannot use the marketing organization of the licensed foreign producer
(D) the licensing company may be supporting a future competitor by licensing a foreign manufacturer

3. The main assumption of traditional forecasting methods is that:

* (A) patterns that occurred in the past will hold in the future
(B) long-term forecasting is more accurate than short-term forecasting
(C) the forecast is independent of the stage in the business life cycle
(D) uncertainty is introduced into the business environment

4. A marketing manager should keep in mind that:

(A) sales forecasts should be developed before marketing strategies are planned
(B) market potential is concerned with how much a firm can hope to sell to a particular market segment
(C) sales forecasts are estimates of what a whole market segment might buy
* (D) The firm's sales forecast probably will be less than the estimated market potential

5. Unlike purchasing by ultimate consumers, purchasing in the industrial market is usually characterized by the fact that:

(A) buyers are not influenced by emotional motives
* (B) direct sales from producer to user is more common
(C) purchases are made more frequently
(D) buyers base their purchasing decisions entirely on company needs

6. Changes in the technological environment affect marketing by:

(A) providing new product opportunities
(B) causing changes in consumer values and life-styles
(C) changing the nature of the media

* (D) all of the above ways

7. A product in the introduction stage of the product life cycle faces a potentially large market and a threat of strong competition. If economies of scale are associated with the production process, what marketing strategy should be used to preempt the competition?

(A) Low promotion and low price
(B) Low promotion and high price
* (C) High promotion and low price
(D) High promotion and high price

8. The objective of product position is to respond to the :

(A) most effective channels of distribution
* (B) customer's perception of the brand in relation to competitive products
(C) degree of elasticity of demand for the product
(D) ratio of gross sales to the projected advertising budget

9. Which of the following factors is a controllable variable?

(A) The economy
(B) The competition
(C) The legal environment
* (D) None of the above

10. The essence of marketing is:

(A) price competition
* (B) an exchange
(C) better products
(D) sales technique

Summary of Marketing Questions

SUMMARY ITEM	N	PERCENT
Number of Students	36	100.0
Average Number of Correct Responses/Question	23.3	
Average Percent of Students Answering a Question Correctly		64.7
Average Number of Correct Answers/Student	6.5	65.0

Note: Excluding Item 2:

Average Number of Correct Responses/Question = 21.9

Average Percent of Students Answering a Question Correctly = 60.8

QUESTIONS FOR ORGANIZATIONAL BEHAVIOR

1. What type of organization is the opposite of mechanistic?

(A) Humanistic
(B) Realistic
* (C) Organic
(D) Chaotic

2. The president of a company is concerned about the high level of interpersonal conflict between the sales manager and the manufacturing manager. Both managers have performed well in their respective departments, but they bicker constantly. The most effective step the president could take to reduce the conflict without sacrificing organization performance would be to:

(A) tell the mangers to get along
(B) reduce the pressure by easing performance expectations
(C) relocate the managers' offices so they would have less contact.
* (D) help the managers to confront conflict

3. Which of the following generalizations [MOST] accurately describes stereotyping?

* (A) Attributing all the characteristics of a class of people to a member of that class
(B) Generalizing an evaluation of one characteristic of a person to other characteristics of the same person
(C) Attributing characteristics of an observer to an individual being observed
(D) Perceiving only those characteristics that satisfy important social needs

4. If the statement "What gets measured gets done" is valid, managers should seek to design which of the following reward systems?

(A) Those that result in equal evaluations of performance by managers and their subordinates
(B) Those that are based solely on quantitative criteria to ensure that rewards are equitably given
(C) Those that provide equal coverage of all the important goals of the organization
* (D) Those that include measurable standards for all important goals

5. Which of the following actions would enrich the design of a job?

* (A) allowing the employee to set the employee's own goals
(B) Providing a more thorough job description
(C) Splitting the job between two positions
(D) Increasing the volume of the work expected

6. What is Fayol's principle of unity of command?

* (A) Each employee should receive orders from one superior.
(B) Each employee's interests are subordinated to those of the group.

(C) Each group of activities with the same purpose has one head and one plan.
(D) Each employee is part of a single effort to accomplish a goal.

7. According to modern organizational theory, an effective organization in a rapidly changing complex environment will need a:

(A) bureaucratic structure
(B) highly formalized operating procedure
(C) mechanistic structure
* (D) highly differentiated structure

8. The organizational structure characterized by grouping of similar occupational specialties is the:

* (A) functional structure
(B) divisional structure
(C) sector structure
(D) simple structure

9. What is an important moderating variable in understanding the likelihood of success of any job enrichment program?

(A) Job rotation
* (B) Employee growth needs
(C) Task meaningfulness
(D) MBO

10. According to expectancy theories of motivation, which of the following outcomes is intrinsic?

(A) Praise from a supervisor
* (B) Personal satisfaction
(C) The respect of fellow workers
(D) A raise in pay

Summary of Organizational Behavior Questions

SUMMARY ITEM	N	PERCENT
Number of Students	35	100.0
Average Number of Correct Responses/Question	22.5	
Average Percent of Students Answering a Question Correctly		64.3
Average Number of Correct Answers/Student	6.4	64.0

QUESTIONS FOR OPERATIONS MANAGEMENT

1.

MONTH	DEMAND	FORECAST
January	550	600
February	580	590
March	560	?

Simple exponential smoothing, with a smoothing factor of .20, is used to track a product. Based on the information shown above, what is the March forecast?

(A) 566
(B) 582
* (C) 584
(D) 588

2. A firm needs 10,000 widgets for a special one-time order. Widgets cost $5.00 each from outside suppliers. The firm can make widgets for $3.00 each if it first spends $10,0000.00 on readily available tooling. What should the firm do?

(A) Buy the widgets from outside the firm
(B) Compute the internal rate of return for widget manufacturing
* (C) Make its own widgets
(D) Make approximately half the widgets and purchase the balance outside

3. Which of the following situations is an example of a job shop?

(A) A car wash
(B) An automobile assembly plant
* (C) A medical clinic
(D) A steel mill

4. Among capacity planning, aggregate output scheduling, and operations scheduling, which usually has the shortest planning horizon?

* (A) Operations scheduling.
(B) Capacity planning
(C) Aggregate output scheduling
(D) All usually have the same horizon

5. Which of the following factors would be the [MOST] important in locating a fast-food restaurant?

(A) Proximity to suppliers
* (B) Access to customers
(C) Cost of utilities
(D) Quality of labor force

6.

JOB	MACHINE A	MACHINE B
1	18	24
2	07	05
3	11	16
4	09	15

Four jobs need to be done in a shop so that the total time to complete all jobs is minimized. All jobs must be worked on first at Machine A and then at Machine B. The standard times in minutes for each job at each machine are shown above. Which of the four jobs should be scheduled to be done [LAST]?

(A) Job 1
* (B) Job 2
(C) Job 3
(D) Job 4

7. To forecast the future demand for personal computers, the statisticians at a firm decide to use time series analysis involving the examination of data describing past demand for personal computers. Which of the following components of this data could they use to make their forecast?

I. Trends
II. Cycles
III. Seasonal variations

(A) I only
(B) I and II only
(C) I and III only
* (D) I, II, and III

8. CAD is an acronym for:

* (A) computer assisted design
(B) complete accounts distribution
(C) commercial applications design
(D) communications access direction

9. Which of the following sets of conditions is typically associated with process layout?

(A) Volume is low, output is standardized, and processing flexibility is not required.
* (B) Volume is low, output is non-standardized, and processing flexibility is required.
(C) Volume is high, output is standardized, and processing flexibility is not required.
(D) Volume is high, output is non-standardized, and processing flexibility is required.

10. Which of the following documents lists all the component parts necessary to produce an end item?

(A) Inventory record
* (B) Bill of material
(C) Dispatch list
(D) All of the above

Summary of Operations Management Questions

SUMMARY ITEM	N	PERCENT
Number of Students	36	100.0
Average Number of Correct Responses/Question	18.9	
Average Percent of Students Answering a Question Correctly		52.5
Average Number of Correct Answers/Student	5.2	52.0

Note: Excluding Item 9:

Average Number of Correct Responses/Question = 17

Average Percent of Students Answering a Question Correctly = 47.2

APPENDIX B

CORE CURRICULUM ASSESSMENT SURVEY

Questionnaire for comparison of COMCORE
and other College of Management Students

SURVEY OF CORE COMPETENCIES

October 1994

As a student in the College of Management (COM) you are required to complete an established group of courses as part of your core requirements. These junior year business courses are Business Finance, Marketing Management, Organizational Behavior, Operations Management, Management Information Systems, and Business, Society and Public Policy. Would you please share your impressions of how these courses have helped you to develop basic business skills and prepare for a business career by completing the following questions?

No.	**Question**	**Strongly Disagree**				**Strongly Agree**
1.	My core courses have prepared me for senior level courses in my area of concentration.	☐	☐	☐	☐	☐
2.	These courses have improved my basic understanding of how business functions such as finance, manufacturing, and marketing "fit together".	☐	☐	☐	☐	☐
3.	I believe that I have a good understanding of how the different departments of a business organization cooperate in managing products.	☐	☐	☐	☐	☐
4.	I am confident that I will be able to make a valuable contribution to my employer's business upon graduation from the BSBA program at UML.	☐	☐	☐	☐	☐
5.	I understand the basic issues involved in introducing industrial product in a foreign market.	☐	☐	☐	☐	☐
6.	I believe that my core experience made me a more confident speaker before groups of business executives.	☐	☐	☐	☐	☐
7.	After completing the core program, I have a good understanding of what must be included in a professional business report.	☐	☐	☐	☐	☐
8.	As a result of my experience in the core courses, I have developed a more professional writing style.	☐	☐	☐	☐	☐
9.	My core courses provided experience to make me a more effective member of a team.	☐	☐	☐	☐	☐
10.	I understand how groups of people work together to complete a joint assignment.	☐	☐	☐	☐	☐
11.	The core program increased my interest in international business issues.	☐	☐	☐	☐	☐
12.	Give your best estimate of your GPA at the end of this term.	______				
13.	I took my core courses in the COMCORE program. (If you took COMCORE program, please provide the information on the next page.)	Yes ☐		No ☐		

APPENDIX C

ORTHOKINESIS, INC.

Case Materials Used in COMCORE B

OrthoKinesis, Inc.
Francistown
Massachusetts

An Integrative Business Core Curriculum Case

Fall, 1994

Braxton Hinchey
David Lewis
Norma Powell
Martin Moser
Yash R. Puri
Chris Tilly

Edited By:
Yash R. Puri

September 5, 1994

Developed under a grant from the Fund for the Improvement of Postsecondary Education, Department of Education, to Dr. Yash R. Puri.

Acknowledgments

Preparation of this case would not have been possible without the help of several individuals who contributed to the process. Significant amount of research was needed to develop these materials. The MBA class of 1994 indirectly contributed to this process. This group completed a study of the orthopedic implants industry as part of the requirements of their Strategic Management course. These studies provided some of the background materials in this case. We are grateful for this help.

Manufacture of orthopedic implants is regulated by the Food and Drug Administration. We are obliged to Mr. Mark Melkerson, Director, Orthopedic Group, Center for Devices and Radiological Health, U.S. Food and Drug Administration, who provided valuable insights into the process. Johnson and Johnson Professional is a leading player in the orthopedic implants area. We are thankful to Dr. Jorge Ochida who organized a tour of the manufacturing facilities for us and provided valuable support and insight into the implant industry. Many members of the staff at Johnson and Johnson helped us during our visit to help make the case as realistic as possible. We are grateful for this support.

Finally, the task of managing various mundane coordination issues had to be carefully orchestrated to bring the case to production in time for the Fall semester. This would not have been possible without the dedicated support of Mr. Curtis Peredina. He provided the support necessary to bring all the materials and information together. We are grateful to him for making this case possible.

B.H.
D.L.
M.M.
N.P.
Y.P.
C.T.

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(C) Promoting & subsidizing businesses
(D) Protecting society against business exploitation

6. In attempting to match individual workers to jobs, managers should consider all of the following characteristics [EXCEPT]:

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(B) knowledge, skills, and abilities
(C) motivational orientations and needs satisfaction
(D) attitudes and beliefs

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(B) Classify jobs according to their relative contribution to organizational effectiveness, but price them according to external labor market rates.
* (C) Classify and price jobs according to their relative contributions to organizational effectiveness.
(D) Classify jobs into a few broad categories and differentiate compensation within categories on the basis of seniority.

8. Which of the following situations is an apparent conflict between Title VII of the Civil Rights Act and affirmative action ?

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(B) Aptitude tests
* (C) Reverse discrimination
(D) Bona fide occupational qualifications

9. All of the following activities are currently advocated by the consumerism movement [EXCEPT]:

(A) disclosing more product information
(B) designing more safety features into products
* (C) placing fewer restrictions on the manufacturers of consumer products
(D) protecting the environment for the consumer

10. Which of the following is the major argument for the deregulation of industry?

(A) it results in higher prices
* (B) it encourages competition
(C) it reduces trade barriers
(D) it shrinks the size of the government

Summary of Business, Society, and Public Policy Questions

SUMMARY ITEM	N	PERCENT
Number of Students	35	100.0
Average Number of Correct Responses/Question	21.6	
Average Percent of Students Answering a Question Correctly		61.7
Average Number of Correct Answers/Student	6.2	62.0

QUESTIONS FOR BUSINESS FINANCE

1. [Ignore tax effects. From which interest table was the figure .91511 probably taken if it came from the row marked by three periods and a column marked 3%?

* (A) Present value of $1
(B) Present value of an annuity of $1
(C) Future amount of $1
(D) Future amount of an annuity of $1

2. [Income Statement]

Revenues	$1000
Operating expenses	400
Interest expense	200
Depreciation	100
Tax rate	40%

Based on the information shown above, what is the cash flow after taxes and interest?

(A) $ 80
(B) 180
(C) 240
* (D) 280

3. A firm sells an average of $20,000 per month on open account. If it increases its accounts receivable annual turnover from 4 to 6, what reduction will occur in the average level of accounts receivable?

* (A) $ 20,000
(B) $ 30,000
(C) $ 40,000
(D) $ 60,000

4. The initial cash outlay for a new computer is $50,000. If a firm has a 10% cost of capital, what is the minimum annual cash flow that would give a positive net present value for the purchase of the computer?

(A) $ 5,000
(B) $ 45,000
(C) $500,000
* (D) Cannot be determined from the given information

5. Apex Company manufactures a product that has a sales price of $54 per unit. Total fixed costs are $9,000 per month and variable costs are $18 per unit. To make a profit in June of $1,800 how many units must Apex sell?

* (A) 300
(B) 180
(C) 150
(D) 90

6. If an account pays 10%, how much must be deposited to withdraw $1,000 per year forever, beginning in two years?

(A) $ 8,264.46
* (B) $ 9,090.91
(C) $ 10,000.00
(D) $ 11,000.00.

7. A company has earnings before interest and taxes of $1,000,000 and has a corporate income tax rate of 40%. The only interest-bearing debt the company has outstanding is a $5,000,000 long-term bank loan at 8%. How many times is interest earned before taxes?

(A) 0.9
(B) 1.5
(C) 1.9
* (D) 2.5

8. A change in the firm's break-even point would [NOT] be caused by a change in the firm's:

(A) variable cost per unit
* (B) corporate tax rate
(C) price per unit
(D) fixed costs

9. Which of the following events will decrease an investment's future annual net cash flows for capital budgeting?

(A) A decrease in the firm's marginal income tax rate
(B) A decrease in the investment's annual fixed costs
(C) An increase in the investment's annual interest expense
* (D) A decrease in the investment's annual depreciation expense for taxes.

10. Based on the actual structure of dividend payout rates across firms, which of the following types of firms will usually have the highest dividend payout ratio?

(A) Fast-growing firms with high-return investment opportunities
* (B) Mature firms with a relatively stable earnings stream
(C) Firms that are closely held by investors in high tax brackets
(D) Firms that have a history of unstable earnings

Summary of Finance Questions

SUMMARY ITEM	N	PERCENT
Number of Students	36	100.0
Average Number of Correct Responses/Question	11.5	
Average Percent of Students Answering a Question Correctly		31.9
Average Number of Correct Answers/Student	3.2	32.0

QUESTIONS FOR MANAGEMENT INFORMATION SYSTEMS

1. How is the data in a computerized business information system organized?

(A) By bytes, bits, nibbles, and lines
(B) By lists, trees, sequences, and structures
(C) By sequential and random structures
* (D) By fields, records, and files

2. Which of the following systems is [BEST] suited for assisting a marketing manager in deciding whether to introduce a new product in a new location?

(A) A database management system
* (B) A decision support system
(C) An electronic data-processing system
(D) A management information system

3. Which of the following statements [BEST} explains the rise in popularity of such input devices as point-of-sale terminals that permit data to be captured at the data-generating event?

(A) They are less expensive than other input devices.
(B) They impress the customer or user.
* (C) They reduce the potential for errors.
(D) They permit faster batch processing.

4. Which of the following definitions [BEST] describes an operating system?

(A) A set of application programs
* (B) A set of programs used to allocate the computer system's resources
(C) A set of programs written by high-level managers
(D) A set of utility programs

5. Text, graphics, or preprinted documents can be transmitted to a remote location by:

(A) an optical character reader
* (B) a facsimile device
(C) a microfiche reader
(D) a shared-logic word processor

6. Compared to an upper-level manager, a lower level manager would have a greater need for:

* (A) real-time information
(B) recurring historical reports
X (C) external information
(D) random access to information

7. The primary objective of a decision support system is to:

(A) provide backup for a manager once a decision has been made
(B) make decisions for a manager
* (C) improve the effectiveness of decision making
(D) help a manager to justify a particular action after it has been taken

8. Which of the following amounts of computer memory storage is equal to 64,000 bytes?

(A) 64 megabytes
(B) 64 gigabytes
* (C) 64 kilobytes
(D) 64,000 kilobytes

9. Which of the following business applications is [BEST] suited for batch processing?

(A) Airline reservations
* (B) Payrolls
(C) Hotel reservations
(D) Hospital medical treatment systems

10. Computers are useful for which of the following tasks?

(A) Speeding up the processing of transactions
(B) Amassing large quantities of data
(C) Improving accuracy and reliability in data processing
* (D) All of the above tasks

Summary of Management Information Systems Questions

SUMMARY ITEM	N	PERCENT
Number of Students	36	100.0
Average Number of Correct Responses/Question	24.8	
Average Percent of Students Answering a Question Correctly		68.9
Average Number of Correct Answers/Student	6.9	69.0

QUESTIONS FOR MARKETING MANAGEMENT

1. Which of the following statements about the marketing role of cultural and social trends is true?

    (A) Marketing managers should attempt to control cultural and social trends.
    (B) Marketing managers should not be concerned about cultural and social trends.
* (C) Marketing mix decisions generally follow cultural and social trends rather than lead them.
    (D) Cultural and social trends have little impact on consumer buying behavior.

2. One disadvantage of using a licensing arrangement to manufacture a product in a foreign country is that:

    (A) the licensing firm then cannot establish its own sales branches to market the product in that foreign country.
    (B) a large investment by the licensing firm is required
    (C) the licensing firm then cannot use the marketing organization of the licensed foreign producer
    (D) the licensing company may be supporting a future competitor by licensing a foreign manufacturer

3. The main assumption of traditional forecasting methods is that:

* (A) patterns that occurred in the past will hold in the future
    (B) long-term forecasting is more accurate than short-term forecasting
    (C) the forecast is independent of the stage in the business life cycle
    (D) uncertainty is introduced into the business environment

4. A marketing manager should keep in mind that:

    (A) sales forecasts should be developed before marketing strategies are planned
    (B) market potential is concerned with how much a firm can hope to sell to a particular market segment
    (C) sales forecasts are estimates of what a whole market segment might buy
* (D) The firm's sales forecast probably will be less than the estimated market potential

5. Unlike purchasing by ultimate consumers, purchasing in the industrial market is usually characterized by the fact that:

    (A) buyers are not influenced by emotional motives
* (B) direct sales from producer to user is more common
    (C) purchases are made more frequently
    (D) buyers base their purchasing decisions entirely on company needs

6. Changes in the technological environment affect marketing by:

    (A) providing new product opportunities
    (B) causing changes in consumer values and life-styles
    (C) changing the nature of the media

* (D) all of the above ways

7. A product in the introduction stage of the product life cycle faces a potentially large market and a threat of strong competition. If economies of scale are associated with the production process, what marketing strategy should be used to preempt the competition?

   (A) Low promotion and low price
   (B) Low promotion and high price
   * (C) High promotion and low price
   (D) High promotion and high price

8. The objective of product position is to respond to the :

   (A) most effective channels of distribution
   * (B) customer's perception of the brand in relation to competitive products
   (C) degree of elasticity of demand for the product
   (D) ratio of gross sales to the projected advertising budget

9. Which of the following factors is a controllable variable?

   (A) The economy
   (B) The competition
   (C) The legal environment
   * (D) None of the above

10. The essence of marketing is:

   (A) price competition
   * (B) an exchange
   (C) better products
   (D) sales technique

Summary of Marketing Questions

SUMMARY ITEM	N	PERCENT
Number of Students	36	100.0
Average Number of Correct Responses/Question	23.3	
Average Percent of Students Answering a Question Correctly		64.7
Average Number of Correct Answers/Student	6.5	65.0

Note: Excluding Item 2:

Average Number of Correct Responses/Question = 21.9

Average Percent of Students Answering a Question Correctly = 60.8

QUESTIONS FOR ORGANIZATIONAL BEHAVIOR

1. What type of organization is the opposite of mechanistic?

(A) Humanistic
(B) Realistic
* (C) Organic
(D) Chaotic

2. The president of a company is concerned about the high level of interpersonal conflict between the sales manager and the manufacturing manager. Both managers have performed well in their respective departments, but they bicker constantly. The most effective step the president could take to reduce the conflict without sacrificing organization performance would be to:

(A) tell the mangers to get along
(B) reduce the pressure by easing performance expectations
(C) relocate the managers' offices so they would have less contact.
* (D) help the managers to confront conflict

3. Which of the following generalizations [MOST] accurately describes stereotyping?

* (A) Attributing all the characteristics of a class of people to a member of that class
(B) Generalizing an evaluation of one characteristic of a person to other characteristics of the same person
(C) Attributing characteristics of an observer to an individual being observed
(D) Perceiving only those characteristics that satisfy important social needs

4. If the statement "What gets measured gets done" is valid, managers should seek to design which of the following reward systems?

(A) Those that result in equal evaluations of performance by managers and their subordinates
(B) Those that are based solely on quantitative criteria to ensure that rewards are equitably given
(C) Those that provide equal coverage of all the important goals of the organization
* (D) Those that include measurable standards for all important goals

5. Which of the following actions would enrich the design of a job?

* (A) allowing the employee to set the employee's own goals
(B) Providing a more thorough job description
(C) Splitting the job between two positions
(D) Increasing the volume of the work expected

6. What is Fayol's principle of unity of command?

* (A) Each employee should receive orders from one superior.
(B) Each employee's interests are subordinated to those of the group.

(C) Each group of activities with the same purpose has one head and one plan.
(D) Each employee is part of a single effort to accomplish a goal.

7. According to modern organizational theory, an effective organization in a rapidly changing complex environment will need a:

(A) bureaucratic structure
(B) highly formalized operating procedure
(C) mechanistic structure
* (D) highly differentiated structure

8. The organizational structure characterized by grouping of similar occupational specialties is the:

* (A) functional structure
(B) divisional structure
(C) sector structure
(D) simple structure

9. What is an important moderating variable in understanding the likelihood of success of any job enrichment program?

(A) Job rotation
* (B) Employee growth needs
(C) Task meaningfulness
(D) MBO

10. According to expectancy theories of motivation, which of the following outcomes is intrinsic?

(A) Praise from a supervisor
* (B) Personal satisfaction
(C) The respect of fellow workers
(D) A raise in pay

Summary of Organizational Behavior Questions

SUMMARY ITEM	N	PERCENT
Number of Students	35	100.0
Average Number of Correct Responses/Question	22.5	
Average Percent of Students Answering a Question Correctly		64.3
Average Number of Correct Answers/Student	6.4	64.0

QUESTIONS FOR OPERATIONS MANAGEMENT

1.

MONTH	DEMAND	FORECAST
January	550	600
February	580	590
March	560	?

Simple exponential smoothing, with a smoothing factor of .20, is used to track a product. Based on the information shown above, what is the March forecast?

(A) 566
(B) 582
* (C) 584
(D) 588

2. A firm needs 10,000 widgets for a special one-time order. Widgets cost $5.00 each from outside suppliers. The firm can make widgets for $3.00 each if it first spends $10,0000.00 on readily available tooling. What should the firm do?

(A) Buy the widgets from outside the firm
(B) Compute the internal rate of return for widget manufacturing
* (C) Make its own widgets
(D) Make approximately half the widgets and purchase the balance outside

3. Which of the following situations is an example of a job shop?

(A) A car wash
(B) An automobile assembly plant
* (C) A medical clinic
(D) A steel mill

4. Among capacity planning, aggregate output scheduling, and operations scheduling, which usually has the shortest planning horizon?

* (A) Operations scheduling.
(B) Capacity planning
(C) Aggregate output scheduling
(D) All usually have the same horizon

5. Which of the following factors would be the [MOST] important in locating a fast-food restaurant?

(A) Proximity to suppliers
* (B) Access to customers
(C) Cost of utilities
(D) Quality of labor force

6.

JOB	MACHINE A	MACHINE B
1	18	24
2	07	05
3	11	16
4	09	15

Four jobs need to be done in a shop so that the total time to complete all jobs is minimized. All jobs must be worked on first at Machine A and then at Machine B. The standard times in minutes for each job at each machine are shown above. Which of the four jobs should be scheduled to be done [LAST]?

(A) Job 1
* (B) Job 2
(C) Job 3
(D) Job 4

7. To forecast the future demand for personal computers, the statisticians at a firm decide to use time series analysis involving the examination of data describing past demand for personal computers. Which of the following components of this data could they use to make their forecast?

I. Trends
II. Cycles
III. Seasonal variations

(A) I only
(B) I and II only
(C) I and III only
* (D) I, II, and III

8. CAD is an acronym for:

* (A) computer assisted design
(B) complete accounts distribution
(C) commercial applications design
(D) communications access direction

9. Which of the following sets of conditions is typically associated with process layout?

(A) Volume is low, output is standardized, and processing flexibility is not required.
* (B) Volume is low, output is non-standardized, and processing flexibility is required.
(C) Volume is high, output is standardized, and processing flexibility is not required.
(D) Volume is high, output is non-standardized, and processing flexibility is required.

10. Which of the following documents lists all the component parts necessary to produce an end item?

(A) Inventory record
* (B) Bill of material
(C) Dispatch list
(D) All of the above

Summary of Operations Management Questions

SUMMARY ITEM	N	PERCENT
Number of Students	36	100.0
Average Number of Correct Responses/Question	18.9	
Average Percent of Students Answering a Question Correctly		52.5
Average Number of Correct Answers/Student	5.2	52.0

Note: Excluding Item 9:

Average Number of Correct Responses/Question = 17

Average Percent of Students Answering a Question Correctly = 47.2

APPENDIX B

CORE CURRICULUM ASSESSMENT SURVEY

Questionnaire for comparison of COMCORE
and other College of Management Students

SURVEY OF CORE COMPETENCIES

October 1994

As a student in the College of Management (COM) you are required to complete an established group of courses as part of your core requirements. These junior year business courses are Business Finance, Marketing Management, Organizational Behavior, Operations Management, Management Information Systems, and Business, Society and Public Policy. Would you please share your impressions of how these courses have helped you to develop basic business skills and prepare for a business career by completing the following questions?

No.	Question	Strongly Disagree				Strongly Agree
1.	My core courses have prepared me for senior level courses in my area of concentration.	☐	☐	☐	☐	☐
2.	These courses have improved my basic understanding of how business functions such as finance, manufacturing, and marketing "fit together".	☐	☐	☐	☐	☐
3.	I believe that I have a good understanding of how the different departments of a business organization cooperate in managing products.	☐	☐	☐	☐	☐
4.	I am confident that I will be able to make a valuable contribution to my employer's business upon graduation from the BSBA program at UML.	☐	☐	☐	☐	☐
5.	I understand the basic issues involved in introducing industrial product in a foreign market.	☐	☐	☐	☐	☐
6.	I believe that my core experience made me a more confident speaker before groups of business executives.	☐	☐	☐	☐	☐
7.	After completing the core program, I have a good understanding of what must be included in a professional business report.	☐	☐	☐	☐	☐
8.	As a result of my experience in the core courses, I have developed a more professional writing style.	☐	☐	☐	☐	☐
9.	My core courses provided experience to make me a more effective member of a team.	☐	☐	☐	☐	☐
10.	I understand how groups of people work together to complete a joint assignment.	☐	☐	☐	☐	☐
11.	The core program increased my interest in international business issues.	☐	☐	☐	☐	☐
12.	Give your best estimate of your GPA at the end of this term.	______				
13.	I took my core courses in the COMCORE program. (If you took COMCORE program, please provide the information on the next page.)	Yes ☐		No ☐		

APPENDIX C

ORTHOKINESIS, INC.

Case Materials Used in COMCORE B

OrthoKinesis, Inc.
Francistown
Massachusetts

An Integrative Business Core Curriculum Case

Fall, 1994

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David Lewis
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Edited By:
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September 5, 1994

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Acknowledgments

Preparation of this case would not have been possible without the help of several individuals who contributed to the process. Significant amount of research was needed to develop these materials. The MBA class of 1994 indirectly contributed to this process. This group completed a study of the orthopedic implants industry as part of the requirements of their Strategic Management course. These studies provided some of the background materials in this case. We are grateful for this help.

Manufacture of orthopedic implants is regulated by the Food and Drug Administration. We are obliged to Mr. Mark Melkerson, Director, Orthopedic Group, Center for Devices and Radiological Health, U.S. Food and Drug Administration, who provided valuable insights into the process. Johnson and Johnson Professional is a leading player in the orthopedic implants area. We are thankful to Dr. Jorge Ochida who organized a tour of the manufacturing facilities for us and provided valuable support and insight into the implant industry. Many members of the staff at Johnson and Johnson helped us during our visit to help make the case as realistic as possible. We are grateful for this support.

Finally, the task of managing various mundane coordination issues had to be carefully orchestrated to bring the case to production in time for the Fall semester. This would not have been possible without the dedicated support of Mr. Curtis Peredina. He provided the support necessary to bring all the materials and information together. We are grateful to him for making this case possible.

B.H.
D.L.
M.M.
N.P.
Y.P.
C.T.

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I. INTRODUCTION

The year was 1957, and Ed Hynes was playing the most intense game of his life. As the first string center for Notre Dame, his career had taken a spectacular turn. If he could hold his ground, playing like he was, he was sure to get a bid for the pros. The emotional and physical high that he felt when crashing through a defensive line, coupled with the heat of the gridiron was all he ever wanted – and here he was. Everyone, including the other team members, knew that he was a natural. Mentally acute, physically adept, and charismatically gifted; the team could count on him and he knew it.

Of more immediate concern was that the person behind him was dependent upon him for this play. It was the cliché fourth down and five yards to go. With only forty yards left to the end zone and ten minutes remaining in the game, their competitors' four point lead left them no choice. Running was their strong point this day, and that was the plan. The hand-off would be to Butczkowski, their quickest running back, who would follow right down the middle behind Hynes. This play would be crucial to their run for the playoffs, and Ed would have to give it everything he could.

In position, he could hear the quarterback volley off the commands.

"Ten!" The crowd roared.

"57!" His hands started to tighten.

"Hut!" He let the ball fly rearward with a brisk snap, while simultaneously lunging forward to meet his 250 pound aggressor. Ed knew as soon as he met with the opposing player that something had gone wrong. The force of the collision with the other player sent Ed off balance and for a moment his legs faltered and sent him crashing into another player closing from the right. Caught between the two, his arm twisted to the rear, and the resulting backward force hyperextended the elbow. That single moment would result in his losing the entire season to a compound fracture of the radial head, and subsequent damage to the articular cartilage. Ed would make it through his Junior year, defying the pain in his elbow, but would be forced to give the sport up shortly afterwards due to the damage suffered that day in September. For the next 20 years he would live with the knowledge that his left elbow was an accident waiting to happen.

* * *

On the way to the hospital, Ed was positive that his elbow had been seriously damaged. As he sat in the passenger seat of the family car, he had a moment to reflect on the incident – the misalignment of the ladder, his fall, and his reaction to break that fall. His wife's concerned look confirmed his fears.

What he did not expect was the final prognosis of his condition. When the doctor informed him that the probability of total recovery was slim, Ed realized the true importance of that day almost 40 years past. The doctor explained the details of his condition.

"You have suffered a great deal of trauma in your elbow. To be specific you have a compound fracture of the radius and humerus, nearest to the joint. The resulting damage to the joint area has led to a buildup of fluid in the articular cavity, which is threatening the integrity of an already worn articular cartilage. What this means in lay terms is that you have badly damaged the end of your forearm and upper arm. The fact that you have already once before injured this area many years ago makes your condition that much worse."

The doctor concluded, " What we're going to do is see how well the bones and cartilage in this area heal. The next few months are going to be critical to this healing process, so don't place any pressure on this arm. The chances of this healing are pretty good, but on the off chance that this area does not fully recover, you will experience limited movement and moderate pain. On top of this, the arthritis has gotten worse in both of your elbows and wrists. The arthritis in this particular elbow will be greatly aggravated by your recent fall."

"I'm going to be totally honest with you Ed – in a case such as this, if the healing does not occur rapidly enough, the pain and limited movement will be enough to cause noticeable discomfort and loss of mobility. In such a case, you would be considered a prime candidate for a total elbow implant. At this time there is a vast amount of new technology in the field of bone reconstruction, and there are new developments every day. But for now, let's concentrate on the healing first – we'll talk more about the implant if needed."

OrthoKinesis, Inc., is a small company in the orthopedics industry. At the present time it specializes in the production elbow implants, and holds a significant share of the market for these implants. These implants are used to replace the natural elbow joint when it gets damaged due to accident or disease. Implants restore only some movement of the joint they replace, and in general cannot provide full functionality of the limb. The elbow replacement market is small. It is part of an industry dominated by several large companies. Most of these companies are engaged in high-volume products – hip and knee replacements. Forces at work in the marketplace at the present time – such as a push towards cost containment in healthcare – threaten the future of the industry. A shakeout in the industry is expected as a result of these forces.

OrthoKinesis is concerned that some of the larger companies will move into elbow production to cushion themselves against this expected shakeout. In order to protect itself in the event that should happen, OrthoKinesis is contemplating diversifying into the production of hip and knee implants. The challenge for OrthoKinesis is to figure out how to take a small company that dominates in one specialized segment of an industry into other segments of that industry already dominated by several larger players.

* * *

II. THE ORTHOPEDICS INDUSTRY[1]

The orthopedic industry at present has about $5 billion in worldwide sales. Although in the past the industry has been growing at about 15-20% annually, this growth is expected to slow down to about 8-10%. This is due to a pressure towards health care cost containment in the United States, which accounts for about two-thirds of industry revenues. The orthopedics industry encompasses many different segments. In addition to implants, such as the artificial elbow, the industry provides services in the area of fixation, casting materials, electrical stimulation products to speed bone healing, and other bone growth factors.

Orthopedic surgery depends upon a vast array of specialized hardware used as fasteners and supports. This segment is called fixation and includes the plates, rods and screws that are used to aid the implant in maintaining the bone structure.

Along with the hardware, the orthopedic surgeon must have specialized equipment that is designed to aid in the diagnostics and insertion of the implant. This segment in the orthopedics industry is known as Arthroscopy and includes the instrumentation and supplies used for the surgical procedures involving the implant.

The plaster and related materials used to construct the casts and molds fall within the segment of casting materials. These are most often used for post operative care and rehabilitation following surgery.

The electrical stimulation segment is comprised of manufacturers of pulse magnetic field equipment used in the treatment of recalcitrant bone fractures and as an adjunct to spinal fusion surgery.

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[1] Data in this section are drawn from March 10, 1994 issue of Industry Strategies by Cowen and Company. A further breakdown of this data is available in that report.

Finally, the industry provides many other products used in orthopedic surgery – surgical instruments, soft goods, and operating room supplies pertinent to orthopedic surgery.[2]

The clinical goal of joint reconstruction is to have a durable replacement; one that will last from 8 to 30 years. In 1993, in the U.S. about 487,000 joint replacements were performed, about 60% of the world market. Currently the average life cycle of a joint replacement is 8 to 10 years.

A. TRENDS IN HEALTH CARE

In the U.S. the trend for health care reform is pushing toward cost containment and managed care. Managed care places some kind of gatekeeper between a primary-care physician and specialized care. Physicians with specialty medicine practices fear that the intrusion of a gatekeeper will diminish the attractiveness of their medical practice. One method of cost containment – fixed-fee reimbursement – clearly places a physician in a position of seeking more conservative treatment for some patients. In addition, various health care organizations are seeking to lower their costs by forming co-operatives so that they can negotiate group contracts and group discounts.

Hospitals are also trying to contain rising costs. For example, they are using just-in-time inventory procedures. Hospitals no longer carry large inventories of diverse medical supplies. Instead, distributors of medical supplies are required to maintain inventories of manufacturer's products so that hospitals may buy on an as-needed basis. Additionally, hospitals are being selective about the procedures they offer. Certain specialized needs are only catered to at selected hospitals.

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[2] Above discussion is based on information in Implants: Reconstructing the Human Body, Wilfred Lynch, Van Nostrand Reinhold Company, 1982, Chapters 1 and 2.

Cost-containment trends are also evident in the orthopedic industry. In 1990, 38 million Americans had arthritis and today the figure has grown to nearly 40 million. By 2020, The Centers for Disease Control and Prevention in Atlanta estimate that 59.4 million people will suffer from arthritis. This increase parallels an aging population, especially the baby boom generation. Already, arthritis is the leading cause of disability in people over the age of 65. A common type of arthritis causes a degeneration of the joint(s) that leads to immobility or pain. However, some current health care plans exclude arthritis treatment. Therefore, even before the push for cost-containment, many people have had to forgo specialized care for their disability.[3]

Currently, growth in the orthopedic market is slowing from double digit (17%) annual growth over 1989-1993 to 8% to 10%. In 1992, orthopedic devices was a $2.7 billion market in the U.S. It rose to $3 billion in 1993, and the 1995 expected market is $4 billion. The U.S. market is about 60% of the worldwide market.

A majority (65-70%) of patients who have total hip replacements are 65 or older and have insurance coverage under Medicare. Given that a total hip arthroplasty (replacement) costs between $20,000 and $30,000 for the total procedure, it is no surprise that the federal government has targeted hip replacement for cost control. The price of the hardware for a hip implant system alone has been rising 5% to 7% annually. In 1993 the price was $3060 and will rise slightly to about $3100 by 1997.

B. COMPETITION IN THE ORTHOPEDICS INDUSTRY

Competition in the orthopedic industry is at two levels – the providers of reconstructive devices and the installers of reconstructive devices. Installers of reconstructive implants are hospitals and their affiliated orthopedic surgeons who compete for patients. Providers of implant devices are a number of firms that produce a variety of implant products. These firms compete for adoption of their reconstructive devices by hospitals and orthopedic surgeons. Competitive analysis at this level requires a careful and complete assessment of a macroenvironment (the industry's environment) and the microenvironment (the specific company's environment). For the orthopedic industry the surgeon is the customer. The orthopedic surgeon is concerned about performance of the prosthesis and the services provided by the implant manufacturer to facilitate a successful surgical procedure. If a company does not provide complete real-time service to the orthopedic surgeon before and during surgery, the surgeon will not even consider using that company's products. Service in this industry is critical and very costly.

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[3] Mary Anne Dunkin and Shelly Morrow, "2020: A vision of Arthritis in the Future," Arthritis Today, July-August 1994, pp. 34-39.

For the surgeon's customer, the patient, satisfactory results from a joint replacement depend on mechanical stability and life of the implant. Mechanical stability depends on three additional critical success factors: (1) the prosthetic design, (2) the surgical preparation of the cavity to receive the prosthesis; and (3) the quality of the host bone. These factors cannot be ignored if the manufacturer of the prosthesis is to be strategically and financially successful.

There are no real substitutes for total joint replacement. However, the changing health care environment will place surgeons in the position of assessing alternative procedures. For example, fewer wrist implant procedures are performed because surgeons are not satisfied with the carpal implant products available. Furthermore, if a rigid cost containment plan is placed upon the health-care industry, surgeons will have to be more conservative in their recommended treatment for joint degeneration, etc., meaning fewer total joint replacement procedures. In either case, it means potential lower sales for the companies that produce joint replacements.

Table II.1 shows estimates of world-wide revenue for firms operating in the orthopedic industry. In the implant segment, hip and knee implants dominate the industry. World-wide revenue for other reconstruction is less than five percent of that for hip and knee reconstruction.

Table II.1[1]
World-wide Orthopedic Industry Segments
1993

Market Segment	World-wide Revenues (MM)
Hip Reconstruction Devices	$1,185
Knee Reconstruction Devices	$1,135
Other Reconstruction Devices	$95
Fixation	$680
Arthroscopy	$403
Casting Materials	$374
Electrical Stimulation	$125
Other	$745

[1] Source: Cowen & Company, Orthopedic Industry, March 10, 1994, p. 3.

The major market for these implants is in the United States. Table II.2 shows the number of procedures performed in the U.S., and the revenue earned in the implant industry by type of implant device. While knee implant devices cost more than the hip implant devices, hip implants command a larger revenue in the marketplace because of the greater number of procedures performed.

Table II.2[1]
Orthopedic Implants in the U.S.

Orthopedic Implants 1993	Number of Procedures	Revenue Per Procedure	Total Market (MM)
Hips	245,000	$3,060	$750
Knees	219,000	$3,240	$710
Other	23,000	$2,390	$55

[1] Source: Cowen & Company, Orthopedic Industry, March 10, 1994, p. 3.

C. THE PLAYERS: COMPANIES IN THE ORTHOPEDIC INDUSTRY

Many companies compete in the various segments of the industry identified above. Market participants in this industry range from companies that primarily produce implant devices (such as Biomet) to implant devices divisions of large pharmaceutical companies (such as Zimmer, which is a subsidiary of Bristol-Myers Squibb). These companies currently offer a variety of products in many different sizes suitable for implant in patients with different characteristics. Highlights of their competitive strategies as identified from their 10-K filings, annual reports, and Cowen and Company report are listed below:

Biomet, Inc.	1992 Revenues: $274,795,000
Biomet was incorporated in 1977 in Indiana. Biomet and its subsidiaries design, manufacture and market both surgical and non-surgical products used by orthopedic medical specialists. Biomet is Headquartered in Warsaw, Indiana.	

DePuy	1992 Revenues: $ unknown
DePuy is privately owned by a German firm named Mannheim Boehringer. DePuy manufactures orthopedic implants. The full range of products is not known. DePuy is headquartered in Warsaw, Indiana. Strategy is unknown. Interest in the shoulder market was mentioned in an interview with a DePuy executive.	

Johnson and Johnson	1992 Revenues: $12.45 Billion
J & J is a worldwide, publicly held corporation. Its business is divided into three segments: Consumer, Pharmaceutical and Professional. The manufacture of orthopedic implants falls under the professional segment which also produces a wide range of products used by physicians, dentist, nurses, therapists, hospitals, laboratories and clinics. Strategy is unknown. Firm has introduced PFC Hip System which gives surgeons the ability to build customized implants in the operating room using a single instrumentation system.	

Kirschner	1992 Revenues: $71,238,000
Kirschner Medical Corporation and its subsidiaries are engaged in the manufacture and distribution of orthopedic and related products primarily to doctors, hospitals and other health facilities in the United States and Europe. Strategic alliance with Figgie International to develop and manufacture custom hips.	

OrthoKinesis	1992 Revenues: $
OrthoKinesis designs, manufactures and markets selected orthopedic reconstructive implant products and related instrumentation. The firm is based in Francestown, MA. Engaged in a exclusive licensing arrangement with the Mayo Foundation to design and develop superior elbow joint implants.	

Pfizer	1992 Revenues: $7,203.2 million
Pfizer, Inc. is a worldwide publicly held corporation. US operations include health care, consumer health care, food science, and animal health. The manufacture of orthopedic implants fall under the Health care division's Hospital Products Group. The firm is headquartered in New York, NY. Innovative and differentiated products. Addressing rising cost of health care with its product offerings. Global focus.	

Smith & Nephew Richards	1992 Revenues: $141.3 million
Smith & Nephew Richards, Inc. is a world leader in the development of biomedical implants, surgical instruments accessories and patient care items. The firm is headquartered in Memphis, TN. Increased emphasis on the development of proprietary products and product improvements to complement and expand existing products.	

Stryker, Corp.	1992 Revenues: $477,054,000
Stryker Corp. and its subsidiaries develop, manufacture and market specialty surgical and medical products, including orthopedic implants, worldwide.	

Dow Corning Wright	1992 Revenues: unknown
A leader in finger joints.	

C. DESIGN AND MANUFACTURING CONSIDERATIONS

The design of an implant device has to achieve a good fit with initial stability, long service life, and lowest possible friction given patient characteristics. The implants are attached to the bone by using a bone cement or a cement-less method. Both types have been found to loosen and produce and discharge implant-material fragments in the vicinity of the reconstructed joint. This can lead to an infection in the area.

Younger, active patients require different type of prosthesis than older, sedentary patients. The industry still does not have enough clinical data to say definitively that one method of

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attaching implants is better than the other. Generally, when a patient is young enough to have good bone stock, cement-less procedures are often followed.

Implant design has an impact on its manufacturing process. In the past, there was little interaction between design engineers and manufacturing engineers during product design. This led to delays and redesign due to manufacturing constraints. Many firms now use integrated product development teams whose members typically contain field marketing representatives, orthopedic surgeons, and manufacturing specialists in addition to design engineers. Further, they have introduced the use of computer-aided-design to assist with new product development. These changes have assisted the industry in reducing the new product design time, and reducing costs in this area.

Many firms have also made significant investments in the recent years in the manufacturing and prototype manufacturing areas. Generally speaking, the move has been towards greater use of computer-controlled (CNC) and robotic machines. These manufacturing trends allow computer generated designs to be programmed on the manufacturing equipment for consistent high quality. Concomitantly, this has caused declining manufacturing employment because a single operator can manage tasks previously performed by several employees. This trend has permeated even the high skill requirement areas of manufacturing where previously manual labor was considered mandatory.

Although the industry has evolved its management practices to become more efficient in product design and manufacture, legal approval processes continue to cause delays in the introduction of new products. Due to the nature of the product – they are implanted within the human body – testing requirements and approval processes continue to be rigorous.

D. THE ROLE OF SAFETY TESTING.

It is impossible to exactly duplicate the environment of the human body, a hostile environment to foreign materials. All materials have to be non-toxic and non-carcinogenic. It is expensive and time consuming to prove that an acceptable level of biocompatibility has been achieved.

Surgeons assist in all product development phases from the design concept to actually "taking a test drive" on a patient. Surgeons take prototypes into surgery and place the prototype in the bone to observe the fit and movement of the new design.

E. MATERIALS

New materials are slow to develop because of the time and expense of safety testing. Basically, implant materials are polymers, metals, and ceramics. Improvements in the metals and plastics presently used are being sought and a bone-like substance, carbon composite, is being developed. Materials that resist wear and oxidation are sought. Please refer to Table II.3 for a comparison of various implant materials.

Table II.3
Comparison of Properties of Implant Materials[1]

	Stiffness		Tensile Strength		Outstanding Characteristics
	psi X 10^5	GP_a	psi X 10^3	MP_a	
Elastomers					
Silicone			.8 - 1.2	5.5 - 8.3	Soft, non-deteriorating
Bion™			1.8 - 2.5	12 - 17	Exceptional flex life
Urethane			2 - 8.4	13.8 - 58	Strong, abrasion resistant
Plastics					
Teflon	0.58	0.4	2 - 5	13.8 - 34.5	Inert
UHMW polyethylene	.2 - 1.1	.14 - .76	5.6 - 6.4	38.6 - 44	Lowest coefficient of friction, high wear resistance
Polysulfone	3.6	2.48	10.3	58.6 - 72	Strong, stiffness close to bone
Acrylic	3.8 - 4.5	2.6 - 3.1	7 - 11	48 - 75.8	Retention of clarity
Polyester	4.6 - 6	3.17 - 4.1	8.5 - 10.5	58.6 - 72	Strong, non-deteriorating fibers
Bone					
Cancellous	1 - 7	.69 - 4.8	12	82.7	Ideal combination of strength, resilience and lightweight
Cortical	10 - 30	6.9 - 20.7	18	124	
Metals					
Titanium Alloy	160	110	146	1006	Corrosion resistant, lightweight
316 Stainless Steel	290	200	140	965	Easily fabricated
Chromium Cobalt Alloy	330	227	155	1068	Wear resistant
Carbon					
Pyrolitic	25 - 45	17 - 31	7	48	Wear resistant, unique tissue compatibility
Fiber	377 - 580	260 - 400	290 - 435	2000 - 3000	Highest strength, unique tissue compatibility

The materials are listed in increasing order of stiffness (tensile modulous) since this is an important physical characteristic when attempting to match the variety of human tissues.

[1] Source: Implants, Wilfred Lynch, VanNostrand 1982

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III: THE BASICS OF JOINT REPLACEMENT

Before taking a closer look at the OrthoKinesis company itself, it is useful to review some of the medical basics of joint replacement.

A. A FIRST LOOK AT JOINTS

A.1. What are joints?

Joints are simply sophisticated hinges linking different parts of the human skeleton. Human joints are, of course, much more complex than the average door hinge. As you can see by experimenting with your wrist, elbow, or knee, many human joints allow rotation as well as flexing. Human bones are linked together at the joints by a variety of soft tissues, including tendons, ligaments, and muscles. In some joints, such as the elbow and knee, there is a sac of fluid (known as the bursa, which is filled with what is called synovial fluid) that acts as a cushion and shock absorber.

A.2. A closer look at the hip, knee, and elbow

Most joint implants replace the hip, knee, and elbow joints. Here is a brief description of each, with medical terminology for the parts of the joints.

The hip is the joint between the femur, or thigh bone, and the coxal (hip) bone, which is part of the pelvis (see Figure III.1)[4]. The entire joint is surrounded by a thick, sturdy capsule of ligaments and other tissues to provide support and assist in moving the leg. The hip is a ball-and-socket joint: the head of the femur is a ball which fits into a rounded hole, known as the acetabulum, in the pelvis. The hip joint permits flexion and extension (lifting and lowering the leg forward), abduction and adduction (swinging the leg to one side or the other), rotation, and circumduction, meaning swinging the leg around in a cone.

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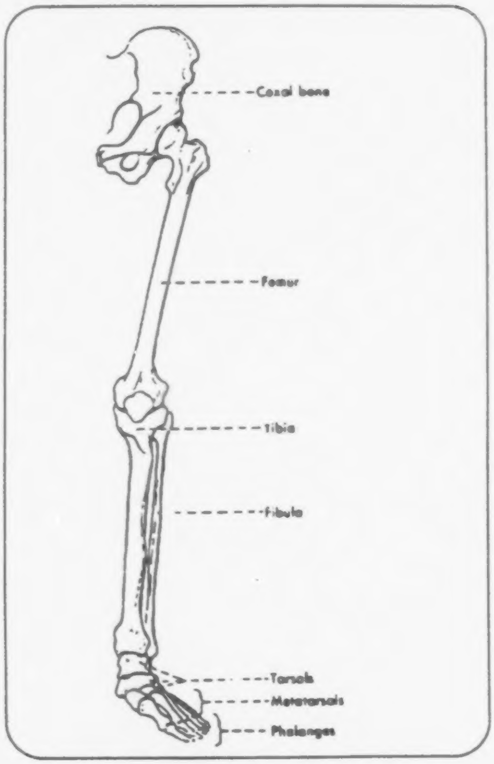
[4] Figures III.1 and III.2 are taken from Hollinshead and Rosse, 1983.

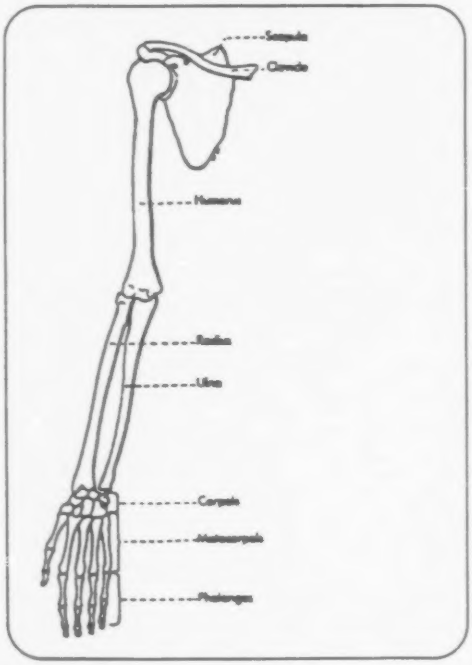
Figure III.1 Lower Limb Structure



The knee joins together the femur (thigh bone) with the two bones of the lower leg, the tibia (shin bone) and fibula (calf bone), which run parallel to each other the length of the lower leg (Figure III.1). Also part of the joint is the patella (kneecap), a smaller bone. The "knobs" at the ends of the femur and tibia that connect in the joint are called condyle. The capsule around the knee joint is much thinner than that around the hip, making knee injuries relatively common. Although the knee is primarily a hinge joint, it can also make other motions including gliding, rolling, and rotation around a vertical axis.

The elbow marks the connection between the humerus (upper arm bone) and the radius and ulna (the two parallel bones of the lower arm) (see Figure III.2). The elbow can be subdivided into the humeroradial and humeroulnar joints (the first linking the humerus with the radius, the second linking the humerus with the ulna). The elbow is primarily a hinge joint. However, in addition to flexion and extension (bending and straightening), the elbow allows supination (turning the lower arm so that the palm of the hand faces forward) and pronation (turning so that the palm faces backward). Like the knee, the elbow joint is surrounded by a capsule that is thin in some parts.

Figure III.2 Upper Limb Structure



B. WHEN IS JOINT REPLACEMENT NEEDED?

Joint replacement, technically known as arthroplasty, is medically indicated when a patient suffers from ongoing pain, immobility, deformity or bone degeneration that cannot be handled by other methods. The most common cause of these problems is arthritis, but they can also result from other diseases or from injuries that fail to heal properly. Unfortunately, an increasingly common condition leading to the need to joint replacement is the failure or degeneration of a previous joint replacement!

Arthritis is a general term for approximately 100 diseases that produce either inflammation of connective tissues, particularly in joints, or non-inflammatory degeneration of these tissues. About one out of seven Americans exhibit some form of arthritis.

C. A THUMBNAIL HISTORY OF JOINT IMPLANTS[5]

The first record of medical use of joint implants, remarkably enough, dates back to 1840. John Murray Carnochan, a New York surgeon, removed part of a patient's jaw joint and replaced it with a small block of wood in order to restore mobility. In the 1880s, Berlin physician Themistocles Gluck developed a system to replace knees, hips, and ankles with ivory prostheses. However, serious development of orthopedic implants began in the 1930s and 1940s, when U.S. surgeons Harold Ray Bohlman and J. Austin Talley Moore replaced hips with metal alloy prostheses. During the 1950s, doctors in a number of countries experimented with hip and other joint replacements, and the field started to take off.

British surgeon John Charnley developed the first practical and economical artificial hip around 1950. Subsequent designs have been based on his approach. An associate of Charnley's, Frank Gunston, in 1968 developed the first artificial knee that was non-hinged, closely approximating the knee's actual motion. In the early 1970s Ralph Coonrad of Duke University developed the artificial elbow that served as the prototype for most future designs. Physicians also invented and perfected prostheses for the shoulder, wrist, and finger joints in the years from the 1950s to the 1970s.

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[5] This history is drawn from Petty, 1991 and Lynch, 1982.

D. MAIN TYPES OF IMPLANTS

There are two main distinctions among implants. One is how much of the joint gets replaced, and the other is the materials and design of the implant itself. This section discusses each in turn.

D.1. How much of the joint gets replaced?[6]

Hip reconstruction may include total hip replacement or partial hip replacement. Total hip replacement, which is more common, replaces the head of the femur (thigh bone) and the acetabulum (the cup in the pelvis). Partial hip replacement only places a new head on the femur.

Knee reconstruction is divided into uni-compartmental knee replacement, bi-compartmental replacement, and tri-compartmental (total) replacement. All three approaches replace parts of the femur (thigh bone) and tibia (shin bone); the difference is how much of the surfaces get replaced, and whether the femur-patella (kneecap) surfaces get replaced. At present, most implants are tri-compartmental.

Finally, elbow replacement may also be partial or total. A partial replacement typically just replaces the head of the radius (one of the two lower arm bones), whereas a full replacement replaces the whole joint.

Most typically, surgeons undertake total replacement when the joint has been damaged by extensive arthritis, whereas partial replacements are more commonly used when an injury has damaged a single bone.

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[6] From Cowen and Crenshaw.

D.2. Materials and design[7]

Orthopedic implants typically use metal (stainless steel, cobalt-chromium-molybdenum alloys, and titanium-aluminum-vanadium alloys), ceramics (which combine metallic and nonmetallic elements), and/or polymer plastics (especially high density polyethylene, called HDP or poly for short). Different materials get used for different parts of the implants: for example most artificial hips feature a metal femoral head (ball) and a polyethylene acetabulum (socket).

Implants are secured in place in a variety of ways. There are four main approaches:

- Mechanical, with some combination of screws, supporting rods, and plates.
- Cement, called poly (methyl methacrylate), or PMMA for short.
- "Press-fit"--simply positioning the implant in a carefully shaped hole in the bone; bone growth then locks it in place.
- Covering implants with a porous coating, so that bone tissue can grow into the tiny gaps in the coating to secure the implant.

Finally, implant designs for elbows and knees can be more or less "constrained." A highly constrained design is hinge-like, permitting only a limited range of motion. Less constrained designs offer a wider range of motion (such as rotation), and rely on soft tissue (ligaments and so on) to hold them in place. Most elbow and knee implants are considered semi-constrained.

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[7] From Crenshaw chapters 40-42, and American Academy of Orthopedic Surgeons.

IV. THE COMPANY: ORTHOKINESIS, INC.

We now return to OrthoKinesis, the implant company that is preparing to diversify from elbow production and launch new knee and hip lines.

A. ORTHOKINESIS: THE BASICS

OrthoKinesis is a publicly owned company with less than 1% of the world market for sales of orthopedic implants. Industry sales are concentrated (90%) in seven companies with sales world wide in excess of two billion dollars.

A.1. Business definition for OrthoKinesis

To promote global health through research, development, manufacture, and marketing of human orthopedic implant systems and supplies. The purpose of OrthoKinesis' products is to ease pain and restore movement.

A.2. Current product interests

Prosthetic Hip Implants - Alice Reardon, marketing manager at OrthoKinesis, estimates that last year's industry sales in hip implants and related instruments were about $750 million in the U.S. Business opportunities in this area involve products directed at: 1) total reconstruction – replacement of the femoral stem, the femur head, and acetabulum; 2) partial reconstruction – replacement only of femoral stem and head; and 3) revision – replacement of a failed or otherwise unsatisfactory implant. Industry sources estimate that the USA represents about 63% of world market potential in this market, and that over the next five years, total sales will increase at a rate of about 5% annually - a significant slowing of previous compound annual growth rates.

Prosthetic Knee Implants - Ms Reardon estimates global industry sales in the knee implant products and instruments to be about $1,135 mm last year, and believes that, as in the case of hips, U.S. market potential is about 63% of global. Categories of knee reconstruction are: 1) total knee reconstruction – replacement of femur and tibia and replacement or resurfacing of patella; 2) uni-compartmental reconstruction – replacement of only one side (femur or tibia) of knee joint; and 3) revision – replacement of a failed implant. As in the case of hip implants, knee replacements are orthopedic solutions to problems related to arthritis and various sorts of bone trauma.

Prosthetic elbow implants - OrthoKinesis currently dominates this small section of the orthopedic industry. And it is small: total 1993 U.S. sales of all orthopedic implants other than hips and knees (including elbows, wrists, shoulders, and fingers) were estimated at $55 million, with world-wide sales at $95 million.

Surgical instruments for implant procedures - All implant companies – and OrthoKinesis is no exception – provide specialized instruments for use during implant procedure. These instruments are specially designed to work with the manufacturer's implant products and facilitate the work of the surgeon. Although a complete set of instruments can cost a significant amount – usually $200,000 to $300,000 – they are seldom sold. The accepted practice in the industry is that a representative of the implant manufacturer attends the surgery makes these instruments available for use by the surgeon during the procedure.

A.3. Growth projections

After several years of rapid growth, growth rates of the orthopedic industry have been slowing down. They are now about half of the growth rates customary ten years ago. Current expectations for the next fiscal year are that the industry sales will grow by about 10%. OrthoKinesis plans to beat this trend. Its press releases to the industry signal the objective of attaining growth at twice the market growth rate for the next 3-5 years. Hence, market share increases for OrthoKinesis will come at the expense of other players in the orthopedic implant market and expansion into new markets. Competition is also expected to increase as a result of cost pressures on hospitals.

OrthoKinesis plans to expand exports to the Pacific rim countries in efforts to achieve 20-25% sales growth in fiscal 1995. Sales to Japan had increased in FY 94 by 71%. The company seeks to increase the number of distributors in Asian markets to pace the planned sales increases. In the domestic market, the firm is proceeding with calculated moves into new sales territories utilizing sales agency agreements in a move to further increase gross profit margins on the firms' product line.

B. PERFORMANCE HIGHLIGHTS

B.1. Growth in sales

OrthoKinesis finished Fiscal 1994 with an impressive 40% growth in sales revenue compared to the previous fiscal year. This was the result of increased unit sales, a shift in marketing distribution channel focus for the firm, price increases in line with inflation and expansion into new markets (see financial data). For investors, the year was the first in the company's history to report four consecutive quarters of profitability and sales growth. Previously, the company performance was erratic and had resulted in large profit and loss swings from one reporting period to the next.

B.2. Major changes in the company

OrthoKinesis was started as a elbow implant distribution company in 1977 by Earl "Colonel" Blaylock, who had started in the health care industry as a sales representative of a pharmaceutical company. Since then, it has gone through three major stages. These stages are briefly listed below.

B.2.a. Distribution stage: 1977-1987

During this time period, the company's business was the distribution of a single product line – elbow joints. Its basic business strategy was based on adding a margin and improving performance by increasing efficiency. During this stage, the company employed about 50 people, mostly sales representatives.

The Colonel had located the company in the Northeast due to heavy concentrations of hospitals in that region. It proved to be a good location as a major segment of the market was in physical proximity. This helped with improved efficiency due to low cost of supporting sales representatives when they were calling on doctors, and closer contact with surgeons in this specialty. The improved efficiencies resulted in OrthoKinesis muscling out a larger share of the market from competitors who were located in the midwestern region of the country.

The organizational chart for this time period was that of a typical distribution company and is shown in Figure IV.1.

OrthoKinesis, Inc. 1977-1987: Sales Force for Distribution

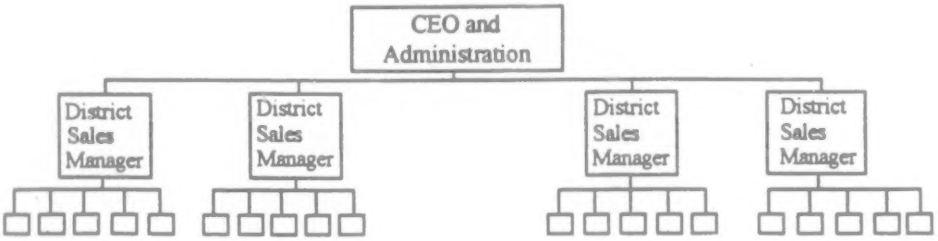

Figure IV.1

B.2.b. Backward integration stage: The past seven years

During this past seven year period, although the company remained in the same product line, it extended its participation in the value chain by developing and manufacturing its own line of elbow joints. During this stage of the company, about 100 people were employed. In order to meet the demands of this backward integration, the Colonel reorganized the company along functional/geographic lines. The organizational chart for OrthoKinesis during this phase is shown in Figure IV.2. (See section IV.E. below, on the value chain.)

OrthoKinesis, Inc: Backward Integration Phase

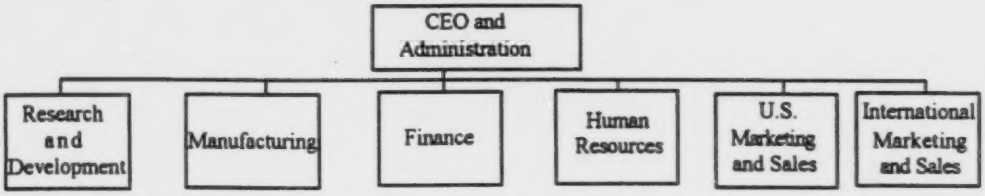

Figure IV.2

Although OrthoKinesis successfully developed their own line of elbows in this phase, morale was low and the Colonel exerted a strong influence on each area.

B.2.c. Growth stage: The past two years

The credit for the OrthoKinesis turnaround belongs to the new CEO Charles Waters. Charles Waters has been involved in this industry for over 30 years. As a result he has business contacts in all segments of the industry. Dissatisfied with the rate of progress of the company, its board of directors ousted the Colonel and brought Mr. Waters in to provide new leadership. Since taking over about two years ago, Waters has used his influence to persuade colleagues from other

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companies to work on his senior management team in OrthoKinesis. While the Colonel had established a very efficient distribution business, OrthoKinesis was lacking in many areas when he moved backwards into design and manufacture. Therefore, the first order of business for Waters was to enhance the firm's operational efficiencies. His management team accomplished that over a two-year period. OrthoKinesis is now in the process of aligning the firm's manufacturing competencies with those of their sub-contractors in order to exploit the best possible value chain business system in the industry. They expect OrthoKinesis and its growing customer base to receive an optimal cost-benefit value from the implant devices supplied by the company.

OrthoKinesis, Inc. Present

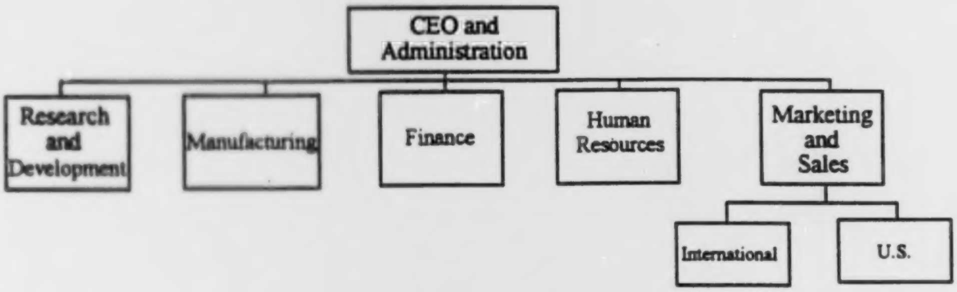


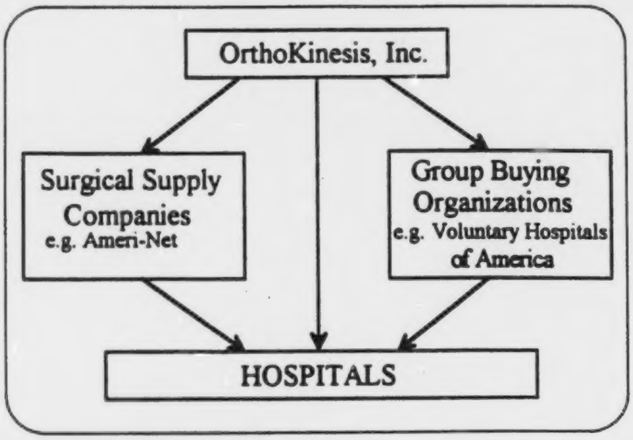
Figure IV.3

B.3. Distribution requirements

Business success at OrthoKinesis requires that its products be preferred by a significant number of orthopedic surgeons and that these preferences be made known to hospital purchasing organizations. For many years, American hospitals have participated in regional purchasing organizations designed to secure quantity discounts for their members. While there is some movement today to purchase high cost items such as orthopedic implants through these group contracts, this requires that some surgeons compromise on the type or brand of implant – a situation likely to be unsatisfactory to high status members of a hospital's surgical staff.

OrthoKinesis can expect to reach its customers – the orthopedic surgeons – through several different channel arrangements outlined in Figure IV.4.

Figure IV.4: OrthoKinesis, Inc. Distribution Channels


OrthoKinesis, Inc.
Surgical Supply Companies
e.g. Ameri-Net
Group Buying Organizations
e.g. Voluntary Hospitals of America
HOSPITALS

Over the last two years, OrthoKinesis has begun to reach out to orthopedic surgeons more actively than in earlier years.

B.4. The Mayo Clinic endorsement

In August of 1994, OrthoKinesis received a major endorsement for its research and development effort in the design and manufacture of elbow joints. It has received a world wide license agreement with the Mayo Clinic to design, manufacture, and market elbow joint implants. Mayo Clinic is a world famous research hospital. The credit for joint research and development work with a premier research institution will provide OrthoKinesis with credibility and visibility among its present and future customer base. As the firm continues with its business expansion plans, this provides OrthoKinesis with several strategic benefits. It can leverage its relationship with the Mayo Clinic to test and receive important feedback for its planned new product lines. It can also leverage this relationship with other orthopedic surgeons and hospitals. It can also potentially use this relationship to influence buying consortia to adopt OrthoKinesis products.

B.5. OrthoKinesis' educational program

The main avenue of generating new customer relationships with surgeons is through educational symposiums and seminars. The value of any surgically implantable product is low (if not zero or negative) when the surgical team responsible for performing the procedure has not been properly trained in installation techniques applicable to the specific implant in use. The prestige associated with working with the Mayo Clinic (finger joint implants) can be leveraged into attracting interest in OrthoKinesis' product line attributes which can be best explained only by competent instruction at a company sponsored seminar.

During 1994 OrthoKinesis sponsored two accredited seminars with nationally recognized facilities. Visibility at the annual American Academy of Orthopedic Surgeons (AAOS) was enhanced by the firms' first scientific exhibit. The opportunity to extend the firms' stature with the customer base at AAOA-sponsored events improves the likelihood of generating individual surgeons interest in company sponsored education.

Out of the first gathering, in January 1994, 40% of the 68 surgeons who attended have since converted to the OrthoKinesis line of orthopedic implants.

C. STRATEGIC CHALLENGES

The most serious of problems that OrthoKinesis faces is a possible shake-up resulting in early consolidation and concentration of the industry brought on by a unique combination of external forces. Recognizing that concentration usually comes in declining industries, OrthoKinesis believes that external forces have combined in such a way that they may induce a pre-decline shake-out of marginally positioned firms.

Information available now suggests that the main thrust of the shake-up will stem from a reevaluation of purchasing practices by hospital buying centers. This reevaluation will include a vendor qualifications process, the net result of which will be to reduce the number of qualified suppliers per hospital. The qualifications process will: 1) favor those suppliers that provide a full orthopedic line; 2) favor suppliers who provide a complete line of implants; 3) favor those suppliers that have the products favored or deemed the most universally acceptable by the highest number of surgeons; 4) favor suppliers who are not only competitively priced but positioned to provide volume discounts 5) favor suppliers positioned for long-term viability; and, 6) favor suppliers whose products are of the highest caliber in design and quality, and whose reputation regarding every aspect of product reliability is impeccable.

If consolidation is triggered by a wave of reductions in qualified suppliers, OrthoKinesis' position is not favorable. During the vendor qualifications process, OrthoKinesis will be at a competitive disadvantage. At the present time it does not supply a full line of orthopedic products or implants. Therefore, it will have difficulty qualifying on the first two benchmarks outlined above. Even if it successfully introduces hip and knee lines in the near future, OrthoKinesis will still have difficulty with item number five. All areas, however, are subject to changes in customer perception and must be negotiated with particular care. OrthoKinesis may be able to leverage its long-standing participation in the industry into convincing buying groups that it is a viable supplier of implants.

There is always the potential problem of lack of leadership at the top levels of the firm. If this happens, the firm could lose valuable time and money in repositioning itself. But the depth of experience and maturity of the new senior staff members, and the strong leadership provided by Waters, make the occurrence of a major strategic blunder very unlikely. The company is well integrated into the orthopedic industry – albeit in a small segment of the industry. Thus OrthoKinesis is knowledgeable about trends and future directions the industry is likely to take. The present management team is proactive in its methods of operations and in the way the firm communicates internally and externally. The firm therefore has the time to react to these trends and develop a long-term survival strategy through product diversification. The personal stakes involved through equity positions – stock ownership and stock option plans – give a high sense of risk and rewards, and provide incentives for senior members of the firm's management team.

In relation to some of the larger firms in the market, OrthoKinesis has limited access to surgeons. OrthoKinesis is small compared to several other companies in this industry. Many of these competitors are division of large pharmaceutical companies. In relation to competitors, OrthoKinesis' contact with potential customers (such as surgeons) and ability to influence the ever-growing base of buying groups is limited. This could be a potential problem, causing loss of future sales and lack of product feedback.

Another area of concern for the growing organization is how to ensure continued growth as a new player in the world market. This is particularly of concern because the firm must maintain its leadership in elbow implants while developing and introducing knee and hip implants. The growth in sales could be interrupted if a major player in the market decides to send OrthoKinesis a signal related to pricing, marketing, distribution or customer service.

Pricing - Limited warfare in OrthoKinesis' sales territories can result in slow growth and damage cash flow needed for operations and research and development because the firm's customer base is so small. However, there are no large players in the elbow implant market.

Distribution - Other market players can place distribution center near OrthoKinesis' clustered Northeastern customer base to signal the firm about expansion plans.

Customer Service - Market players can invest more funds into increased levels of customer service which OrthoKinesis may not be able to afford to match. "If this happens, we are dead," marketing manager Alice Reardon commented recently.

Marketing - Medical symposiums can be monopolized by large players with slick, expensive presentations, in an effort to crowd out small firm exposure.

It is clear that the top players are large multinational corporations. These are the firms that have the financial capability to invest substantially in research and development for the length of time it takes to get FDA approval to market a product. In addition, they have the infrastructure to market their products in lesser developed countries and in countries where the approval processes may provide fewer constraints, and by building on the learning curve in this way, they may leverage the introduction of products into the United States.

Because of large company dominance of the much of the orthopedic market, smaller companies are being forced to reinvest in other subsegments of the market and to gain efficiencies in existing traditional markets. This maneuvering is characterized by new strategic alliances and research and development expenditures in the targeted area. In addition, adjustments are being made to distribution channels, pricing and promotion. Meanwhile, the search for a technology that would revitalize the hip replacement market continues.

D. ORTHOKINESIS' STRATEGIC RESPONSE

This analysis has significant implications for OrthoKinesis. Sales and profit performance accomplished during the last year and winning an exclusive license with a premier research hospital demonstrate OrthoKinesis' capabilities. The strategy for survival and growth in the face of the threat of being muscled out of the market by larger competitors is based on this capability. OrthoKinesis CEO Charles Waters and his management team have decided that the best defense is a good offense. Since offering a full range of implants provides a key competitive advantage, they have decided to expand their offerings, adding hip and knee implants to the elbow implants they now manufacture.

OrthoKinesis sees several reasons for anticipating success in this endeavor. From a design point of view, elbow are more complex. This is because elbow joints must provide for turning in addition to bending. Its recognition as a quality elbow manufacturer speaks highly of its research and development team. Designing the simpler knee and hip implant devices by this team should results in products that offer serious competition to the existing lines. OrthoKinesis is also presently updating its manufacturing facilities. In order to maintain its quality, it is desirable to acquire state-of-the-art computer controlled equipment to maximize its manufacturing flexibility. Such equipment is, however, difficult to justify based on the small quantities of elbows required annually. Adding knee and hip implant lines will lead to fuller utilization of these machines, making the investment justifiable. This will increase OrthoKinesis' options for financing the acquisition of this equipment. OrthoKinesis also now has a close link to orthopedic surgeons at Mayo. It will be able to use this relationship to test its knee and hip implant designs. OrthoKinesis also has a well established sales force. This sales force will need new training and fresh leadership, but changes in the marketing and sales area planned which will make significant impact in this area.

E. VALUE ADDED VERSUS VALUE CHAIN

As they hammer out a strategy for the company, CEO Charles Waters and other top executives draw on two related conceptual frameworks: the value chain and cost structure analysis. While these concepts are relevant for any business, they are particularly useful for a company planning a major change – such as OrthoKinesis' planned move into hips and knees.

Until recently, in U.S. businesses, each organizational department's focus was largely internal to the firm. Each organizational unit viewed its activities in the context of the work they performed, what it cost to do the work and what they received for their work, that is, their purchases, processes, products, and customers. Their concern started with payments to suppliers (purchases) and stopped with the charges to customers (sales). The key theme was to maximize the difference between purchases and sales, or the value added.

One of the major themes of cost management efforts takes a broader approach and focuses on what Michael Porter calls the value chain. "The value chain for any firm in any business is the linked set of value-creating activities - from basic raw material sources to the ultimate product or service that is delivered to consumers."[8] A firm may perform activities in only a portion of the value chain. Activities are simply the work that a company does. Each distinct value activity performed is a building block by which a company creates a product/service that has value to its current and potential customers. As you move through the value chain, a company's resources are either transformed into value-adding products and/or services, or the resources are wasted. Cost management primarily concentrates on two items: identifying activities that do not add value and seeking continuous improvement in all other activities.

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[8] Barry J. Brinker (Editor), *Handbook of Cost Management 1993 Edition*, Warren, Gorham, and Lamont, 1992, p. D1-2.

However, by looking at the entire chain a strategic insight emerges that is better than the more narrow internal view. Various organizational units are still concerned with the value added concept but have to keep that in perspective with the value chain. Most relationships in the chain are both supplier and customer. These relationships may be internal or external to the firm. Workers have to challenge the performance of the relationships repeatedly to find a quicker, cheaper, better way to perform their work. To prosper, a company needs to be able to "transform" better than its competitors.

F. COST STRUCTURE ANALYSIS

What or how a company is doing is always determined relative to its competitors. Is the product/service as good as or better than a competitor's product? Is the delivery of the product as timely or better than a competitor's delivery? Is the total cost the company spends to provide the good or service more than, less than, or the same as the major competitor? Remember that selling price, cost, and profit are interrelated. Strategic cost factors determine a company's relative long-term position. A firm's cost structure refers to the types of costs incurred in delivering that firm's product or service to its customers. Companies have to keep costs in line with their competitors or risk damaging their competitive position. A value chain serves as a framework to develop a cost structure. How might the cost structure differ? Differences can occur anywhere in the value chain, for example:[9]

1. Differences in prices paid suppliers of the inputs to their processes.

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[9] From Thompson and Strickland, Strategic Management, 1992, pp. 90 - 91.

2. Differences in the age and type of plant and equipment.
3. Differences in internal operating costs associated with economies of scale, productivity levels, wage rates, overhead-type costs, tax rates, etc.
4. Differences in transportation costs, inbound and outbound.
5. Differences in marketing costs.
6. Differences in forward-channel costs.

An example of a Cost Structure for Prostheses Product:

I. Materials
    A. Purchasing department
    B. Ingredients
    C. Inbound Shipping
    D. Warehousing
II. Manufacturing Costs
    A. Direct product costs:
        1. Raw materials
        2. Direct labor
        3. Packaging
        4. Depreciation
    B. Indirect product costs
III. Marketing costs
    A. Distribution channel costs
    B. Sales Representatives
    C. Market research
IV. Customer service
    A. Surgeon relations
    B. Distributor relations
V. General and Administrative costs
    A. Finance and accounting
    B. Legal services
    C. Regulatory costs
    D. Executive salaries
    E. Taxes

V. ORTHOKINESIS PERSONNEL

OrthoKinesis presently employs over 100 people. While a significant group is from the time period of Blaylock, CEO Waters has made several changes in the management team of the company since taking control of OrthoKinesis in 1992. In a few areas, where managers were performing satisfactorily, he has kept the people hired by Blaylock. But in other areas, where the Colonel had promoted incompetent people so that he could retain control over those areas, Waters has hired new people. The following section describes the present management team of OrthoKinesis.

A. THE MANAGEMENT TEAM

The credit for the OrthoKinesis turnaround belongs to the CEO, Charles W. Waters. He brings over 30 years of industry experience and business contacts to the company. Since taking over in 1992, Waters has developed a highly skilled and varied management team. In a 24 month period, operational deficiencies were corrected and enhanced. OrthoKinesis is now in the process of aligning its manufacturing competencies with their subcontractors' in order to exploit the best possible value chain system. Waters received his BA from the University of Massachusetts at Dartmouth in 1961 and an MS from the Massachusetts Institute of Technology in 1969.

Waters took over from Earl "Colonel" Blaylock. The Colonel started the firm in 1977 as a distribution company. As a young boy his dream was to become a doctor. He got a degree in Biology in 1958 from the Virginia Military Institute and then went into the military. After getting out, he became a sales representative in a pharmaceutical company. His next job was as a purchasing agent in a hospital, where he conceived the original idea for OrthoKinesis. He established the company in Francistown in southeastern Massachusetts in 1977.

Waters recruited two players on the management team from outside the company – Nick "Rocco" Gargiulo, VP of R&D, and Zelda Goldstein, the CFO. Gargiulo received his BSME from the University of Lowell in 1963. Waters first met Rocco at a fraternity function. Gargiulo got his Ph.D. in Mechanical Engineering at RPI in 1971. Goldstein received her BA in Math from Wellesley in 1986, and obtained an MBA from Harvard in 1991. Waters recruited her from a top notch management consulting firm.

The remainder of the management team are holdovers from the Blaylock regime. The VP of Manufacturing is Ricardo Santiago. Santiago is a Cuban immigrant who got a BSME from Florida State in 1972 and an MBA from Rice in 1972. The Human Resources VP is James "Jim" McCord, a 1959 Sociology graduate from the City College of New York. Alice Reardon is the Marketing and Sales Manager. Previously she was head of international sales. Her promotion now has international (an unoccupied position at present) and the National Sales Manager, Talmadge "Buddy" Gooden, reporting to her. Previously, she and Buddy were at the same level. Reardon received her BSBA from UConn in 1970 and an MBA from SUNY Buffalo in 1975. Gooden got his BS in Political Science from VMI (the Virginia Military Institute) in 1964. He is a Vietnam vet, and had met Earl Blaylock while he was in the service.

This reorganization in the marketing and sales area is due to an expanded role for the marketing function in the company. Responsibilities for the marketing manager at OrthoKinesis are described in the next section.

B. KEY RESPONSIBILITIES OF THE MARKETING MANAGER AT ORTHOKINESIS

1. In the New Product Development Process: a) Manage relationship between OrthoKinesis' team of consulting orthopedic surgeons and principals in research and development

to ensure that sound ideas for new products and meaningful product improvements continually move from the operating room to our design center; b) Estimate market potential for new product concepts; and c) Manage the introduction of new products through creation and execution of sound marketing plans.

2. General Responsibilities: a) Recruiting, selecting, training, motivating, evaluating, controlling, and compensating OrthoKinesis' field sales force. The company's success depends on extremely close cooperation (often in the operating room) between its sales representatives and the customer, that is, surgeons. OrthoKinesis must supply surgeons with the parts, tools, and supplies necessary to do their jobs accurately, quickly, and with a minimum of trauma to their patient. Surgeons must also know who we are and what OrthoKinesis stands for. The surgeons must trust the sales representatives and respect them as health care professionals. b) Promotion in addition to personal selling is critical to the success of OrthoKinesis. For each product line the marketing manager must develop appropriate advertising and sales promotion plans consistent with the company's communications goals.

VI. THE REGULATORY ENVIRONMENT

Like any company, OrthoKinesis must concern itself with a wide variety of federal, state, and local government regulations. These regulations cover everything from environmental protection to employment discrimination, from stock issuance to zoning. But OrthoKinesis' top executives worry most about two areas of regulation: the Food and Drug Administration's product approval process, and the federal government's regulation of health care financing. This section provides a fairly detailed discussion of FDA approval, and a shorter review of health care financing issues.

A. FOOD AND DRUG ADMINISTRATION PRODUCT APPROVAL

A.1. Overview of device regulation by the FDA[10]

Orthopedic implants are considered medical devices. The category of devices is a broad one, taking in just about everything intended for medical use that is not a drug--from toothbrushes to magnetic resonance imaging (MRI) machines. Devices have--in theory--been regulated by the federal government's Food and Drug Administration (FDA) since the 1938 Food Drug and Cosmetic Act, but the regulations were quite loose until the adoption in 1976 of the Medical Device Amendments to that Act. Additional amendments in 1990 and 1992 further tightened up the regulations. The particular section of the FDA responsible for devices is the Center for Devices and Radiological Health (CDRH).

The Medical Device Amendments require manufacturers to obtain FDA approval before putting any new device on the market. The amount of evidence needed for approval depends both on how much the device differs from products already on the market, and how much risk is likely to be associated with it. When Congress passed the Amendments in 1976, they were reacting to "horror stories" such as pacemaker failures and the Dalkon Shield intrauterine device, a birth control device that killed 20 women, caused infections in tens of thousands more, and led to unexpected pregnancies in 110,000 women--ending in miscarriage over half the time.

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[10] In addition to the sources cited in the text, this section draws heavily from O'Reilly 1993, Chapter 18, Industry Surveys 1993, and Ingersoll 1992.

Both businesses and consumer advocates were unhappy about how the FDA carried out the 1976 Amendments. In a 1980 survey, 47 percent of device manufacturers gave the FDA a negative overall performance rating, compared to 43 percent who rated it positively (Committee on Energy and Commerce 1983). Manufacturers complained of paperwork, high costs of compliance, and difficulty in obtaining technical assistance and compliance information. On the other hand, consumer advocates and members of Congress criticized the FDA for its slowness in setting up standards for safety and effectiveness, and its decision to grandfather all devices in use before 1976. As part of the Reagan administration's goal of deregulating business, the agency did relatively little to place limits on manufacturers. "Horror stories" began to mount up again during the 1980s. Journalist Herbert Burkholz comments that during this decade, "The FDA was perceived as bumbling and inefficient" (1994, p.1).

But over the last few years, two changes have enhanced the FDA's reputation in device regulation--at least as far as consumers are concerned (many businesses are still displeased!). First, the 1990 and 1992 Amendments strengthened the FDA's regulatory powers. Second, and perhaps even more important, in 1990 President Bush named a new FDA Commissioner, Dr. David Kessler, who shook up the agency and brought a more energetic and aggressive approach to regulation. In 1993, Dr. Kessler named Dr. Bruce Burlington to head the Center for Devices and Radiological Health. Unlike his predecessors, John Villforth (director from 1982-1990) and

James Benson (director 1990-1993), who took a minimalist position on regulating devices, Dr. Burlington is expected to take an activist stance. He came from 12 years of regulating drugs, which have always been far more closely scrutinized than devices.

A.2. Specifics of FDA device regulation[11]

Regulatory requirements differ between devices marketed prior to the 1976 Amendments, and devices brought on the market after that date. Manufacturers may continue marketing pre-1976 devices without obtaining any added approval from FDA, until 30 months after the FDA sets standards for these devices. Because the FDA has been very slow to set such standards, this provision has so far amounted to grandfathering almost all devices in use before 1976, as pointed out above. However, Congress has ordered the FDA to complete its review of pre-1976 devices by the end of 1995.

New devices are another matter. The FDA classifies all new devices into Class I, II, or III, from lowest to highest patient risk. Higher classes place added requirements on manufacturers. Relatively few orthopedic products--manual surgical instruments such as chisels, fiberglass or plaster cast materials, and a few others--fall into Class I, the low-risk category that includes tongue depressors and toothbrushes. Most orthopedic implants end up in Class II, but a few are in Class III. Semi-constrained, cemented hips and knees are in Class II, and uncemented knees were recently (in early 1994) moved from Class III to Class II. Noncemented artificial knees and resurfacing prostheses (prostheses that replace just the surface of the bone rather than the entire end of the bone) remain in Class III, the class that includes high-risk items such as artificial hearts.

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[11] This section draws from: O'Reilly Chapter 18, Center for Devices and Radiological Health 1992A and 1992B, Melkerson 1994, Ingersoll 1992, and Industry Surveys 1993.

So what difference does it make what class your device ends up in? Table VI.1 shows the regulations the FDA imposes on manufacturers of each class of devices.

Table VI.1
FDA requirements for each class of devices

	Class I	Class II	Class III
General Controls			
Manufacturing site registration	X	X	X
Official listing of devices	X	X	X
Pre-Market Notification	X	X	X
Good Manufacturing Practices	X	X	X
Reporting of post-market problems	X	X	X
Special Controls		X	X
Must have Pre-Market Approval OR FDA must find "substantial equivalence"			X

As the table shows, some requirements--the "General Controls"--apply to all device makers. Manufacturers must register each manufacturing site with the FDA, updating the registration annually. This requirement actually extends to distributors as well, so that OrthoKinesis had contact with the FDA even when it was simply distributing other companies' products (although that contact was limited to submitting a one-page registration form!). Each device must also be listed on another one-page form. A company intending to market a new or changed device must submit a Pre-Market Notification to the FDA, with information about the device. Finally, device makers must carry out FDA-specified Good Manufacturing Practices, which cover design, methods, facilities, and controls in manufacturing and shipping devices--with a major emphasis on quality assurance. Somewhat stricter GMP requirements apply to "critical"

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devices, which include all implants. Finally, manufacturers must report to the FDA any incidents in which a device appears to have failed or caused serious injury to a patient.

Class II devices are subject to "Special Controls." These controls vary depending on the product, but may include:

- labeling requirements
- recommended or mandatory performance standards
- post-market surveillance of device performance, which may include maintaining a directory of all patients using a given device.

In the case of implants, the FDA does require tracking of patients.

Finally, Class III devices face the strictest regulation. To market a Class III device, the manufacturer must do one of two things. Their first option is to provide a Pre-Market Notification demonstrating to the FDA that the device is substantially equivalent to a pre-1976 device, or to any other device that has already been approved by the FDA. Alternatively, the company can submit a Pre-Market Approval Application (PMAA) with scientific evidence documenting that the device is safe and effective.

Here's the catch: all new devices are initially classified into Class III. It's up to the company, through a Pre-Market Notification or Pre-Market Approval Application, to convince the FDA that the product either belongs in another class, or is a safe and effective Class III product. In short, the devices are "guilty until proven innocent"--perhaps not unreasonable for products that may mean life or death for consumers.

In practice, most companies seek to demonstrate that a new product is substantially equivalent to previously approved products. This course of action costs far less than conducting research to prove a device's safety and effectiveness.

Before the 1990 Amendments, documenting substantial equivalence was in many cases as simple as submitting photographs of an earlier product and the new product. But some companies abused this process. For example, in 1980 medical supplies giant Baxter Travenol submitted a Pre-Market Notification for a volumetric pump cassette, a small, disposable plastic part used in regulating intravenous fluid flow to a patient. As evidence of substantial equivalence, Baxter sent a photograph of a cassette (a pre-1976 product) made by another company, IMED, an alleged photograph of Baxter's cassette, and copies of the labeling for the two products. It turned out that the second photograph was of a doctored IMED cassette--Baxter had not yet created a prototype of their own cassette! Evidence later emerged that the first two generations of Baxter's cassette sometimes leaked, leading to potentially life-threatening situations. The FDA did not punish Baxter except to require that it contact its customers and warn them of the danger. This low-key approach enraged some in Congress, providing some of the impetus for the 1990 and 1992 Amendments.[12]

The 1990 Amendments beef up the evidence required for a Pre-Market Notification. Manufacturers are at least supposed to provide a literature search for evaluations of the earlier product, and device testing may be needed if the new product has significant technological differences.

The need to prove substantial equivalence to an existing product can lead to conflict within a company. As food and drug law expert James O'Reilly points out, "Marketing managers always seek out what is new, better, improved, and different.... `Substantial equivalence' is the last thing a marketing person wants to advertise for an improved product." But, he warns, advertisements must be carefully worded, lest they bring unwanted attention from the FDA (for selling a product that is not substantially equivalent) or the Federal Trade Commission (for deceptive advertising).[13] Non-compliance with either agency's regulations can lead to problems for the new product and the company.

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[12] Committee on Energy and Commerce 1983, pp. 35-47.

The new, tighter Pre-Market Notification requirements, as well as the more stringent regulatory stance championed by FDA Commissioner Kessler, have slowed down the FDA's device review process in recent years. The FDA's Center for Devices receives about 5,700 Pre-Market Notifications per year, but was only able to approve 2,500 of them in fiscal 1992, down from 3,000 in fiscal 1991. The Center gets 60 to 70 Pre-Market Approval Applications per year, but approvals dropped from 47 in fiscal 1990 to 12 in fiscal 1992. FDA approval currently takes 6 to 12 months, and many fear that the logjam is only going to get worse (Industry Surveys 1993).

So as OrthoKinesis prepared to launch its new hip and knee product lines, company executives knew they would need to convince the FDA that their product was substantially equivalent to products already on the market – while convincing potential buyers that these products were superior. They knew that the duration of the approval process was unpredictable – and that approval itself was not a sure thing. Given the complexity of the regulations, they became quite familiar with the 800 number of the Center for Devices' Division of Small Manufacturers Assistance. (Incidentally, this Division received high marks from businesses even in the 1980 survey that revealed such negative attitudes toward the FDA overall: over three-quarters of manufacturers who had contacted the Division found it helpful.) They also knew they would have to purchase advice from a lawyer with expertise in food and drug law in order to avoid running afoul of the law.

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[13] O'Reilly 1993 18.34-18.35.

B. FEDERAL REGULATION OF HEALTH CARE FINANCING

The federal government is the largest purchaser of health care in the country. Through the Medicare program, it pays for guaranteed health care for all of the elderly. Other large buyers of health care--the states (through their Medicaid programs which pay for health care for families falling below a certain income line, partly financed by the federal government) and many private insurers (Blue Cross/Blue Shield and all the rest)--model their rules on the federal government's Medicare regulations. So directly or indirectly, the federal government has set the guidelines for health care financing since the 1960s--even without a health care reform law. For orthopedic implants, the federal impact is even larger, since 65-75 percent of implants are paid for by Medicare (Pluemer et al 1994).

Soon after the federal government launched Medicare and Medicaid in the 1960s, it became clear that health care costs were a serious problem, as they spiraled upward. Health care providers (doctors and hospitals) charged Medicare and Medicaid on a "cost-plus" basis--charging the costs of the treatment plus a margin to cover overhead. In response, the federal government moved toward stricter and stricter cost controls. At first, they just required "peer review"--organizations of doctors and hospitals periodically reviewed a sample of medical records from each health care institution to ensure that only needed care was being provided. But beginning in the late 1970s, they began experimenting with "diagnosis related groups." Health care providers are required to classify each patient's illness and treatment into a diagnosis related group, or DRG. The federal government then sets a maximum amount that the provider can charge for each diagnosis.

Although DRGs were initiated in the late 1970s, it took years for them to have major effects. But at present, their effects are felt strongly. For example, hospitals strive to discharge patients as quickly as possible to keep costs under the DRG limit, and emphasize home care rather than inpatient care. Many smaller community hospitals have merged or gone out of business, and even industry giants such as Boston's Massachusetts General Hospital and Brigham and Women's Hospital have merged. Streamlined corporate hospital chains such as the Hospital Corporation of America (which was acquired by Columbia Healthcare, another hospital chain, late in 1993) have snapped up a large share of the market (often buying up failing hospitals), using aggressive cost management measures. Some critics argue that these changes have kept costs somewhat in check, but at the expense of reducing the level of patient care.

The implications for orthopedic implant manufacturers are straightforward. Cost containment has put a lid on the amount that insurers reimburse hospitals for orthopedic procedures, but the prices of the implants themselves have continued to rise rapidly. This cannot continue indefinitely, and there is already evidence that price growth is beginning to moderate in the implant market.

Consider total hip replacement. During the 1980s, according to research by Dr. William Healy of the Lahey Clinic in Burlington, MA, total hospital costs for hip replacement grew by only 2 percent after controlling for inflation. Meanwhile, hip implant costs grew by 118 percent after controlling for inflation! The implants shot up from 11 percent of the hospital's costs for the operation in 1981 to 24 percent in 1990 (Stephenson 1994). Another estimate puts implant costs at 44 percent of the hospital's total cost of hip replacement--over $3,000 out of a total cost of $9,000-11,000. In many cases, hospitals actually lose money on implant surgery.

What's more, surgeons are keenly aware that their own fees--from $1,200 for a partial hip replacement to $2,400 for a revision (repair) of an artificial knee or hip--are far less than implant costs. And the federal government's recently implemented Resource-Based Relative Value Scale targets orthopedic surgeons for fee cuts totaling 9 percent between 1992 and 1996 (Pluemer et al 1994).

Not surprisingly, doctors and hospitals have responded by trying to find ways to reduce implant costs. Some of the steps they have taken include:

- Simply taking cost into account in shopping for implants. Historically, surgeons have been much more conscious of quality, and have taken little note of costs. That is changing.
- Sharing price information with other hospitals, and negotiating for bulk discounts through group purchasing contracts--something that hospitals have long done with other kinds of supplies[14].
- More carefully matching implant types to patients--using more durable and costly implants for younger and healthier patients, and cheaper implants for patients who are older or in poor health. The price differences are substantial: a "low demand" hip suitable for a less active patient with a short expected life-span costs $965-$1,915, whereas a "high-demand" hip can run $2,950-$5,200[15].
- "Recycling" implants that are opened in the operating room but never used, which were previously thrown out. At one New York hospital, this has led to recycling dozens of implants a year, at savings of tens of thousands of dollars[16].

Given all of these changes, industry experts predict a slowdown in price increases.

How much difference would a new national health plan make? At the time of writing this case, it is unclear what type of health plan, if any, will get passed during the Clinton administration. However, several facts cast a threatening shadow on orthopedic implant manufacturers:

1. Regardless of when or whether health care reform becomes law, the debate over health care reform focuses health care providers' attention on costs--and implant costs are an obvious target.

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[14] Wagner 1991

[15] Pluemer et al 1994

[16] Stephenson 1994

2. Again, whether or not health care reform passes this year, it is likely to be enacted some time in the next several years. And when enacted, cost containment provisions will surely be part of it.
3. As pressures for cost containment rise, orthopedic surgery will be a natural place to cut back. Unlike a heart disease patient who needs a bypass graft, an arthritis sufferer is not likely to die if a doctor delays surgery and treats the condition with drugs. As a result, physicians will be likely to turn toward more conservative (non-surgical) approaches to orthopedic problems.
4. Implant and other medical device manufacturers found a couple of proposals floated by the Clinton administration particularly unnerving. One proposal was for a national health-care review board to determine whether new technologies are cost effective, even after FDA approval. This was dropped from the plan President Clinton finally offered, but could reappear in the future if the Clinton plan fails. Another is that the Regional Health Alliances--the large coalitions that would pay for health care--could potentially set across-the-board, binding price controls on medical goods and services. Again, Clinton's actual plan emphasizes targeting and bargaining rather than explicit price controls, but some medical suppliers claim this amounts to "hidden" price controls.

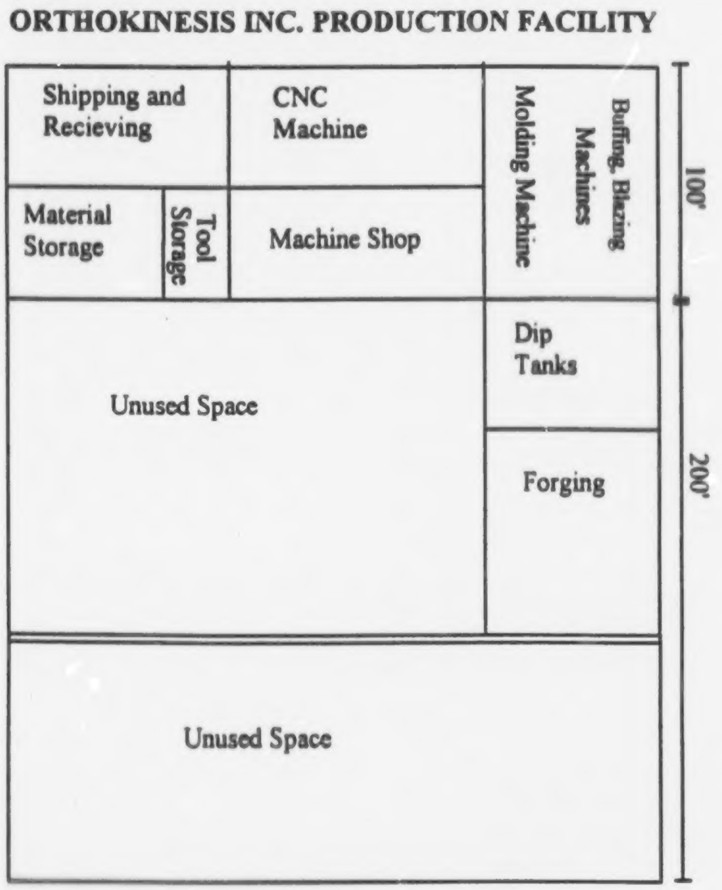
The future of health care policy remains uncertain, but what is certain is that with or without a new health plan, the government's drive to control health costs is not going away. This makes introducing a new orthopedic implant risky.

VII. MANUFACTURING AND FACILITIES REQUIREMENTS

The types of equipment necessary to produce knee and hip replacement is similar to that needed to produce elbows. The existing facility should be able to incorporate the proposed product lines. However, there are potential changes in amount of equipment and production labor force which will be needed. These issues are discussed in the sections below.

A. PHYSICAL FACILITIES

The production facility at the present time is located in an old mill building. The current facility layout is shown in Figure VII.1.



ORTHOKINESIS INC. PRODUCTION FACILITY

Figure VII.1

A 1,000 square feet of space is being used in the production area, with another 19,000 square feet available for expansion. Thus, the current facility should be able to handle any increased demand for elbows or the space required to produce the proposed knee and hip lines for the foreseeable future.

Note that the machinery has been set up in a job shop type of layout with similar machines and processes being located in the same areas. This type of arrangement has worked fine in the past given that OrthoKinesis is only producing one product line, but changes may have to be made if the proposed expansion goes forth.

B. PRODUCTION PROCESS

Currently, OrthoKinesis is producing 10,000 elbows each year for a very specialized market. These elbows are produced in six basic sizes. There are three basic components to the elbow replacement: the replacement joint (top piece), the joint cup (middle piece), and the replacement stem (bottom piece). The replacement joint/joint cup are made so that they match (that is, they come in sets), and the stem replacement varies in complexity depending on the amount of bone deterioration. A general description of the steps involved in the production of the three components (and the location of these steps in the above facility) is outlined below:

B.1. Joint replacement

The elbow joint is cast from a cobalt chromium alloy. The basic process is similar to creating fancy dishes from clay molds. Currently, wax molds are created for each joint by a molding machine. These molds then go through a series of dips where the wax is coated with a ceramic material. There are three dips in total which have to monitored very carefully in terms of temperature, length of dip and consistency of dip to create a stable and solid shell. This shell will remain intact even when exposed to very high temperatures. The resulting ceramic covered wax mold is then heated slightly and the wax removed. The resulting hollow mold is then sent to a forge where liquid cobalt chromium is poured in. This casting is then cooled at room temperature. After a 24-hour cooling period, the ceramic shell is cracked off, and the finished casting is removed. There are then four more steps in the process which are to fine tune polish the finished joint. These operations are called glazing, polishing, buffing, and cleaning. These are equivalent to using various grades of steel wool and sand paper on your car. Although they appear simple, the glazing operation especially requires a great deal of skill to know where and how much pressure to place on the casting.

B.2. Joint cup

The joint cup must be married to the joint replacement described above. The fitting of this marriage is very important since friction is created with the constant movement of the joint once it is implanted into the user. The process to make this piece is relatively simple. Plastic polyethylene sheets are machined into the right sizes. OrthoKinesis has already invested in computer numerically controlled machinery (CNC), which can perform a number of machining operations. The current CNC machine has fourteen tools, thus allowing the machine to be programmed to do 14 different machining operations. The elbow joint cup requires use of seven of these tools to perform operations such as machining the cup bottom (where it snaps into the joint stem), machining the outer part (so it fits into the cavity of the old joint), and forming the cavity which will interact with the replacement joint. The cavity operation takes the most time and requires the closest tolerances since this is the moveable portion of the reconstruction assembly.

The current CNC machine works on both the joint cup (which is a plastic material) and the joint stem, a metal, which has caused some maintenance and scheduling problems.

B.3. Joint stem replacement

The last major piece in the elbow replacement system is the stem replacement. This system takes on a number of forms depending on the amount of good bone tissue available. Ideally, the system will use as short a stem as possible. The core material is usually titanium, although a cheaper polyethylene material can be used. The major problem with the polyethylene is expected life, as this material disintegrates much quicker. Currently the company buys castings which are in the general shape of the elbow stems. The same Hitachi-Seiki CNC used for the joint cup machines the stem. However, the processing time is much longer than with the plastic, and the tool wear must be watched much more closely. Currently, three tools go through a computerized sequence: face milling, drilling, and tapping the stem. The incomplete stems are then sent out to a vendor who performs a sintering operation. This operation basically creates a rough surface on the metal stem which will cause the bone to adhere to it better. This requires a very expensive machine with a very low cycle time, thus no consideration has been given to performing this operation in house. After sintering, a plastic coating is applied to the stems by the same vendors.

Once the sintered stems are received back from the vendors, they go again to the machining center where the pockets are tapped. This is another dimension which must be closely monitored. Each stem is then sent to the inspector where key dimensions are gauged through 100% inspection.

In addition to the CNC machine, there are is a small machine shop, which contains all of the metal working machines necessary to create the parts. This machine shop is rarely used now except in helping to prepare prototypes, and handle small 1-2 part rush orders that cannot be scheduled on the CNC machine. These machines include shearing, milling, drill and tap, and molding. All of them are at least 40 years old.

Table VII.1
OrthoKinesis Production Equipment

Machine	Value (new)	Current age	Capacity
Joint replacement			
Molding machine	$10K	25 years	1/hr
Ceramic dipper (3 tubs)	$500K	25 years	2/hr
Hot Metal Forge	$500K	10 years	4/hr
Glazer/polisher/buffer (6 available)	$25K	20 years	1/hr
Cleaning tank	$15K	15 years	20/hr
Joint Stem			
Hygain-telex CNC	$120,000	12 years	1/hr
Stem Replacement			
Hygain-telex CNC (same as joint stem)			1/hr
Miller	$25K		
Drill and tap (2)	$25K		
Shearer	$25K		
Molder	$20K		
Shipping			
Sealer	$2K	10 years	10/hr

As seen above, there is some equipment within the process which is being used nearly to capacity. The Hygain-telex CNC machine where the elbow joints are formed is a critical area, currently running three shifts and weekends. Additional equipment will have to be purchased in this area. For planning purposes, it is estimated that production times for knees and hips are similar to the times developed for the production of elbows.

The final step is preparing the materials for shipment. This is more critical than with most consumer products as the pieces must be irradiated and stacked in the boxes in a specific fashion.

Currently the three components are placed manually in a box which is then placed in a sealer which automatically seals the boxes for shipment.

The present lead time – time between an order being placed and being filled – is eight weeks.

Table VII.2 shows the current staffing and production shifts in manufacturing.

Table VII.2
OrthoKinesis Manufacturing Staff and Production Shifts

Machine	Number of Operators per Shift	No. of Shifts Run*
Joint Replacement		
Molding Machine	1	3
Ceramic Dipper (3 tubs)	1	2
Hot Metal Forge	1	1
Glazer/Polisher/Buffer (6 available)	6	1
Cleaning Tank	1	1
Joint Stem		
Hygain Telex CNC	1	3
Stem Replacement		
Hygain Telex CNC	(same as joint stem)	
Miller	3 machinists for all machines	1
Drill and tap (2)	used only for low volume parts	1
Shearer		
Molder		
Shipping		
Sealer	2 people employed in packaging	1
Others		
Inspectors	5 (one for each component)	1
Final test	2	

There are many ideas available for potential process improvement and capital equipment decisions which must be made before OrthoKinesis can go forth with the new product lines.

C. MANUFACTURING LABOR FORCE REQUIREMENTS

The direct manufacturing labor force for elbow manufacturing consists of thirty full time workers. Twenty are production workers, with five being assigned to inspection, two to the tool crib, and three to material storage. In addition, there are three employees assigned to the loading dock (during the first shift only), and one foreman production control specialist to each shift. Specific assignments are listed below.

The most significant problem with the present manufacturing set up is that the jobs are of varying skill levels. The highest skill levels are associated with the CNC machine operators and the machinists. The lower skills are required of the packaging and inspection stations. One goal of the corporation is to cross-train these individuals. This is desirable to develop a flexible manufacturing environment. The operators in the non-machining section of the joint replacement group spend a good deal of their time monitoring the machines which themselves are only occupied a small percentage of the whole time.

D. CURRENT COST OF PRODUCTION

Currently, the elbows, are sold for $3025.00. The current market share is 40% of a total market of 24,000. That is, they produce 10,000 elbow implants per year. This sales price represents on average a 65% profit margin. Thus, on average the cost of goods sold is approximately $900.00. This breaks down as follows:

Material:	45-60% of cost
Labor:	20-30% of cost
Disposable overhead:	5-10% of cost
Overhead:	10-15% of cost
Subcontracted parts:	10-15% of cost

D.1. Labor costs

The production workers are paid between $25,000 and $45,000 per year, depending on their level of expertise. This breaks down to $12.50 to $22.50 per hour or on average $17.50 per hour. The cost of fringe benefits is around $10/hour. There are on average 10 hours of direct labor, including inspection, packaging, and shipping and receiving, that go into the average total elbow replacement. Thus, the average cost of labor is about $275.00 per elbow joint. A process flow chart, with approximate labor times, is shown in Figure VII.2.

D.2. Material costs

Material costs depend on the material used in the joint replacement. The metal in the joint replacement, cobalt chromium, is quite expensive. There is relatively little waste, as this metal is poured into a mold . On average, this breaks out to $150.00 per piece. The most expensive material is titanium which costs on average $225.00 per piece. This is partly because there is a relatively large percentage of waste, 15-20%, as the piece has to be formed into shape. The last piece, the polyethylene costs about $50.00 per piece, but here again the cost of the waste is high due to the cutting of the polyethylene sheets. Waste is 25-30% per sheet.

Thus total materials cost is about $425 per total elbow assembly.

D.3. Disposable overhead

Disposable overhead amount is charged at about $50 per elbow. This includes the wax molds, the cleaning fluids, cooling fluids for the machine tools, and other disposable items.

D.4. Overhead

Overhead is charged at about $75 per elbow. This includes everything else needed to run the manufacturing operation, including electricity to run the machinery, heating and lighting, and other similar items. This also includes all the tools and dies for the machine tools and the CNC machine.

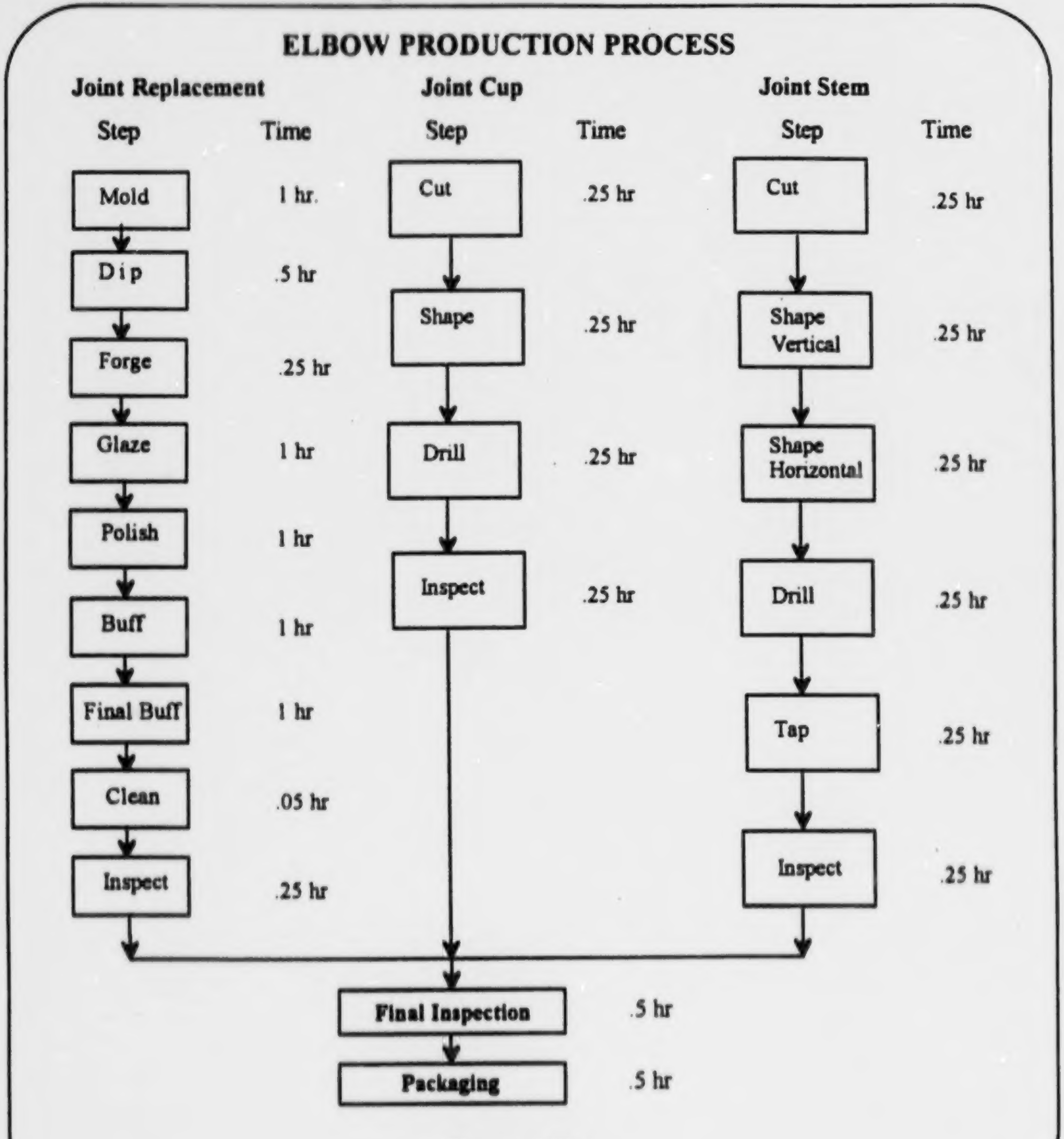


Figure VII.2

D.5. Subcontracting cost

As indicating in the description of the production process, there is one operation which is subcontracted out. This is the sintering operation. This piece of equipment is very expensive, and thus no thought is currently being given to moving it in house. The subcontracted cost per unit is about $100.00 per unit.

E. CURRENT PRODUCTION PLANNING AND CONTROL SYSTEMS

The company currently produces to order. Most orders are on the order of 3-25 elbows, thus requiring the frequent setting up of the machinery. Very archaic inventory control systems are in place as everything except for the polyethylene and the metals is kept in a stocking area, and orders for new materials are placed when the material level falls below a visual limit. A simple economic order quantity system is used for the other parts and raw materials.

The quality control system is primarily manual and uses preset gauges which determine the critical dimensions of the pieces after completing the machining operations. A final visual inspection is also done to check for impurities. Almost no in-process control is used.

The most labor intensive operations are the grinding and buffing operations. Each stage of the buffing process takes about an hour and there are four stages. These operations require a high degree of skill and chances for error are high. One of the major decisions which must be made in expanding the line is whether to replace the old machine tools with robots which are capable of doing all of the operations. These robots cost on the order of $500,000.

As mentioned earlier, the CNC machine is running near capacity. Increasing production in this product line or entering new product lines is likely going to require significant decisions of capital equipment acquisition. Choices range from traditional machine tools at $25K per crack to first generation CNC machine tools at $100K to the state of the art machine tools at $500K each. These new tools allow for quick change overs, important to an industry such as this one where order quantities are always going to be low.

These are just some of the issues production will be facing as it gets ready to move into expanding into new product lines.

VIII. FINANCING

Financing considerations for OrthoKinesis will be primarily driven by the need to expand into the new markets for the company. Some of the projections prepared by OrthoKinesis are presented here.

A. SALES PROJECTIONS

OrthoKinesis believes that most of this year will be required to develop and test its new knee and hip lines. Following this new product development phase, OrthoKinesis plans to initially sell these products outside the U.S. while waiting for approval from the FDA for marketing in the U.S. It is optimistic that this approval will be obtained within one year following the introduction in the international market. Based on this analysis, it has developed some early projections. Table VIII.1 shows some of the estimates developed by OrthoKinesis.

Table VIII.1
OrthoKinesis Development Projections
Hips and Knees

Market	Year			
	Current: t	t+1	t+2	t+3
U.S. Market Share	Product Development Phase	None	About 1%	About 2%
Outside U.S. Market Share		About 1%	About 1.5%	About 2%

Detailed financial statements for OrthoKinesis are presented in the appendix. These include Balance Sheet and Income Statements for the past five years. In addition, average financial ratios for the orthopedic industry are also included in the appendix. OrthoKinesis is evaluating its expansion plans and expects to add new manufacturing equipment in the future to

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support new and existing product lines. Equipment may be purchased or leased. The financing decision will depend on the firm's capacity to raise new capital, and the cost of raising these funds. Therefore, OrthoKinesis is evaluating cost of raising new funds.

B. COST OF CAPITAL

Interest rates on a variety of financial instruments are presented in Table VIII.2. As you can see from this table, interest rates are relatively high. OrthoKinesis does not want to commit to a long-term cost of capital that may lead to a strategic disadvantage. It therefore intends to move towards a capital structure that includes sufficient long term financing for the growth expected in the hip and the knee business.

Table VIII.2
Interest Rates for the Past Ten Years

Year	prime rate	treas 6-mo	treas 3-yr	treas 10-yr	corp aaa	corp bbb
Current	7.91	6.56	7.29	7.35	8.04	9.11
Last Year (t-1)	7.96	6.85	7.02	6.67	7.03	7.81
t-2	6.3	5.47	5.68	5.65	6.18	6.94
t-3	5.61	4.63	5.03	5.07	5.51	6.23
t-4	5.63	5.08	5.23	4.92	5.13	5.67
t-5	4.54	4.05	4.22	4.28	4.49	4.87
t-6	4.5	3.69	4.03	4.19	4.4	4.83
t-7	4.5	3.25	3.67	4	4.26	4.86
t-8	4.5	2.91	3.47	3.95	4.33	5.02
t-9	4.5	2.61	3.54	3.88	4.35	5.08
t-10	4.82	3.25	3.98	4.12	4.41	5.19

OrthoKinesis has traditionally followed a very conservative debt policy. Its debt to equity ratios have traditionally been significantly below the average for the orthopedic industry. This conservative stance was also the reason it chose the use of preferred stock about four years ago, rather than raise additional debt.

OrthoKinesis believes that its conservative financing practices in the past will pay rich dividends in future. It expects that it will be able to raise new capital with reasonable cost of capital now that it is planning a major expansion into new product areas.

C. STOCK HISTORY

OrthoKinesis currently has 5,005,000 shares outstanding. When Charles Waters took over as the CEO of OrthoKinesis, the stock market reacted positively. In expectation of strong future performance, the stock price jumped by $2 per share within a month of his joining the company and has been staying in that range. Waters took advantage of this market optimism by issuing new shares to raise about $6 million in new equity capital. Most of the capital raised was utilized to finance the high growth experienced by the company since he joined.

OrthoKinesis stock is currently trading at $8.50 per share. The stock price had jumped to $9 per share when the company posted the high growth of the recently completed fiscal year. The low for the stock has been $6.0 per share over the past couple of years. The company does not pay a common stock dividend, and is current on its dividend payments on the preferred stock.

IX. SUMMARY

OrthoKinesis is presently facing several strategic decisions. It is faced with a health care outlook where a consolidation among the companies involved seems inevitable. OrthoKinesis is a small player in the overall market for orthopedic joint reconstruction market, but a significant player in the niche area of elbow replacements. It is concerned that due to the relatively small size its long-term survival may be threatened by consolidation in the orthopedic industry.

It is reinvigorated by a new management team brought in over the past two years. This team has been successful in halting the decline of the firm in its niche market and has posted impressive growth in this market in the recent years. It has secured significant endorsement from a leading research hospital. The stock market has reacted positively to the new management team and the stock is trading near all time high.

The new management team has decided to diversify into the business of hip and knee joints. This market segment is dominated by several large players. These companies are well established in this business. Yet, it appears that the international market is largely unexploited. OrthoKinesis is certain that the established players in the market will begin a push in this area to cushion themselves against consolidation.

Having decided to engage in this battle, OrthoKinesis must efficiently and quickly introduce its hip and knee lines. Other than the consolidation threat it sees, OrthoKinesis is not burdened by any significant problems. It has no major law suits against it. It is liked by the town where it has been located since its inception. It has been a good corporate citizen and has provided steady employment opportunities. The new push will undoubtedly create new jobs in the area. Yet, to be successful, it must be aggressive in new product development.

APPENDIX D

ORTHOKINESIS, INC.

Appendices to OrthoKinesis, Inc.

A.1. ORTHOKINESIS BALANCE SHEET

OrthoKinesis, Inc.
ANNUAL BALANCE SHEET
($ MILLIONS)

	Year				
	t-1	t-2	t-3	t-4	t-5
ASSETS					
Cash & Equivalents	7.02	3.02	0.26	0.07	0.24
Net Receivables	3.74	3.65	4.68	4.09	3.17
Inventories	6.96	5.82	6.96	7.2	8.6
Other Current Assets	0.22	0.41	0.38	0.39	0.28
Total Current Assets	17.93	12.91	12.28	11.74	12.27
Gross Plant,Property & Equip	7.78	7.89	7.52	5.95	4.1
Less: Accumulated Depreciation	4.87	4.29	3.46	2.52	1.52
Net Plant,Property & Equip	2.9	3.61	4.06	3.44	2.59
Other Assets	0.54	0.14	0.08	0.16	0.12
TOTAL ASSETS	21.38	16.65	16.42	15.33	14.98
LIABILITIES					
Long Term Debt Due In One Year	0.41	0.29	0.25	0.21	0.08
Notes Payable	0	0	2.57	0.45	1.6
Accounts Payable	1.95	1.16	1.68	0.47	2.48
Other Current Liabilities	1.77	1.29	1.46	0.72	0.67
Total Current Liabilities	4.13	2.74	5.95	1.85	4.82
Long Term Debt	0.83	0.85	1.02	1.05	0.61
Deferred Taxes	0	0	0	0	0.04
EQUITY					
Preferred Stock	1.27	2	2	2	0
Common Stock	0.47	0.44	0.31	0.3	0.29
Capital Surplus	17.23	15.3	9.97	9.62	8.98
Retained Earnings	-2.55	-4.66	-2.83	0.51	0.25
Less: Treasury Stock	0	0	0	0	0
Total Common Equity	15.15	11.07	7.45	10.44	9.51
TOTAL EQUITY	16.42	13.07	9.45	12.44	9.51
TOTAL LIABILITIES & EQUITY	21.38	16.65	16.42	15.33	14.98

A.2. ORTHOKINESIS INCOME STATEMENT

OrthoKinesis, Inc.
ANNUAL INCOME STATEMENT
($ MILLION)

	Year					
	t-1	t-2	t-3	t-4	t-5	t-6
Sales	29.37	21.08	20.12	18.13	14.01	9
Cost of Goods Sold	8.97	7.62	6.91	5.12	3.92	3.01
Gross Profit	20.4	13.46	13.21	13.01	10.08	5.99
Selling, General, & Admn Expenses	15.93	12.74	12.53	10.73	10.15	7.37
Operating Income Before Deprec.	4.47	0.73	0.68	2.29	-0.06	-1.39
Depreciation, Depletion, & Amort.	1.8	1.66	1.5	1.05	0.64	0.36
Operating Profit	2.67	-0.93	-0.82	1.24	-0.71	-1.75
Interest Expense	0.29	0.37	0.26	0.3	0.13	0.09
Non-Operating Income	0.26	0.12	0.03	0.02	0.02	0.02
Special Items	0.75	-0.52	-2.19	-0.59	0.02	0.34
Pretax Income	3.38	-1.71	-3.24	0.37	-0.8	-1.48
Total Income Taxes	1.15	0	0	0.14	-0.1	-0.49
Minority Interest	0	0	0	0	0	0
Income Before EI & DO	2.22	-1.71	-3.24	0.23	-0.69	-0.99
Extraordinary Items (EI)	0	0	0	0	0	0
Discontinued Operations (DO)	0	0	0	0	0	0
Net Income	2.22	-1.71	-3.24	0.23	-0.69	-0.99
Preferred Dividends	0.11	0.12	0.12	0	0	0
Available For Common	2.12	-1.83	-3.36	0.23	-0.69	-0.99
Savings Due Common Stk Equiv	0	0	0	0	0	0
Adjusted Available for Common	2.12	-1.83	-3.36	0.23	-0.69	-0.99
Dividends Per Share	0	0	0	0	0	0

A.3. INDUSTRY AVERAGE FINANCIAL RATIOS

Orthopedic Industry
INDUSTRY AVERAGE FINANCIAL RATIOS

	t-1	t-2	t-3	t-4
LIQUIDITY				
Current Ratio	2.17	2.12	1.94	2.94
Quick Ratio	1.39	1.38	1.23	1.77
ACTIVITY				
Inventory Turnover	3.01	2.76	3.47	N.A.
Receivables Turnover	5.13	4.85	6.56	N.A.
Total Asset Turnover	1.14	1.11	1.48	N.A.
Average Collection Period (Days)	71.19	75.22	55.64	N.A.
Days to Sell Inventory	121.27	132.43	105.3	N.A.
Fixed Asset Turnover	4.19	4.32	4.2	4.22
PROFITABILITY				
Operating Margin Before Depr (%)	17.88	17.24	17.96	14.26
Operating Margin After Depr (%)	14.39	13.95	14.6	11
Pretax Profit Margin (%)	11.69	13.37	12.96	9.72
Net Profit Margin (%)	7.49	8.85	8.27	5.97
Return on Assets (%)	7.62	9.31	8.75	6.68
Return on Equity (%)	16.06	19.48	21.15	12.06
Return on Investment (%)	11.67	14.78	14.42	9.2
LEVERAGE				
Interest Coverage Before Tax	4.96	6.41	4.76	6.36
Interest Coverage After Tax	3.54	4.58	3.4	4.29
Long-Term Debt/Common Equity (%)	32.11	24.06	36.31	30.45
Long-Term Debt/Shrhldr Equity(%)	31.91	24.01	36.21	30.26
Total Debt/Invested Capital (%)	37.66	37.03	48.7	31.89
Total Debt/Total Assets (%)	24.59	23.33	29.55	23.13
Total Assets/Common Equity	2.11	2.09	2.42	1.81
DIVIDENDS				
Dividend Payout (%)	6.9	3.45	4	9.3

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OrthoKinesis, Inc.

Glossary of Orthopedic Terms

acetabulum	a large cup shaped, cavity containing the ball-shaped head of the femur
allograft	the transfer of tissue between two genetically dissimilar individuals of the same species, such as a tissue transplant between two humans who are not identical twins.
arthroplasty	(artho - to join, fit; plasty - plastic surgery involving a part) the surgical reconstruction or replacement of a painful, degenerated joint, to restore mobility to a joint in osteoarthritis or rheumatoid arthritis or to correct a congenital deformity.
carpal	of or pertaining to the carpus (8 bones arranged in two rows), or wrist
cement	a material used in the fixation of a prosthetic joint in adjacent bone, such a methyl methacrylate.
condyle	a rounded projection at the end of a bone that anchors muscle ligaments and articulates with adjacent bones; forming a ball-and-socket joint
endocrine	pertaining to a process in which a group of cells secrete into the blood or bymph circulation a substance that has a specific effect on tissues in another part of the body.
endocrine fracture	any fracture that results from weakness of a specific bone because of an endocrine disorder
femoral components:	
	straight-stem prostheses
	anatomically shaped prostheses
	modular prostheses
femoral	of or pertaining to the femur or the thigh.
high molecular weight polyethylene (HMWPE)	
hip joint	coxal articulation
lunate bone	a carpal bone
medial	situated or oriented toward the midline of the body
metabolic	of or pertaining to metabolism. the aggregate of all chemical processes that take place in living organisms
metallurgy	the science of metals
orthopedics	the branch of medicine devoted to the study and treatment of the skeletal system. its joints. muscles. and associated structures.

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In the Land of the Orthopedic Implant

Warsaw, Ind., center of the industry, is leery of health reform.

By BARNABY J. FEDER

WARSAW, Ind.

HERE in the town that is to bone surgery what Detroit is to cars and Hollywood is to movies, the inability of Congress to agree on health care reform is widely seen as a blessing. Not only is the northeastern corner of the state politically conservative, but some of the measures that have been proposed could make life difficult for orthopedics manufacturers, a $6 billion-a-year industry born here nearly a century ago.

Manufacturers of artificial knees, hips and other orthopedic devices based here these days include Zimmer, a Bristol-Myers Squibb Company subsidiary that is the market leader; DePuy Inc., a Corange Ltd. subsidiary that was the industry pioneer, and Biomet Inc., a fast-growing, publicly traded upstart. These companies, along with smaller competitors and suppliers, helped Warsaw sail smoothly through the recessions that rocked most of the Midwest during the 1980's. They account for more than 40 percent of the nation's output of orthopedic implants, a share that has been creeping up as they acquire smaller players.

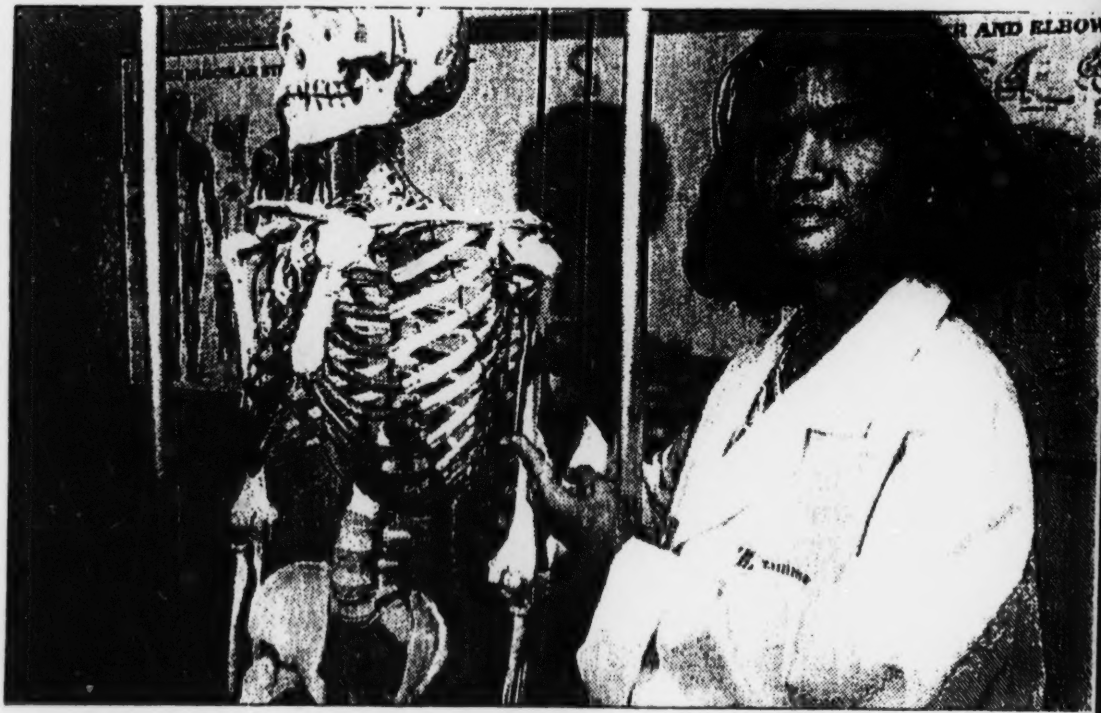
"We are sympathetic to their complaints of overregulation," said Jeffrey Plank, Warsaw's mayor, smiling at the understatement.

Warsaw's special ties to the orthopedics industry are not immediately obvious to a visitor to the community, which has 11,500 residents. The town is home to other manufacturers, including a mammoth R. R. Donnelley & Sons printing plant that employs 1,550 people and is about to expand. And Warsaw is the commercial heart of Kosciusko County, one of the nation's most fertile farming regions and a popular resort area because of its many lakes. There are no statues of the orthopedics industry's founders, no parks or schools named after them, and the local school mascot is not a surgeon but a tiger.

Still, Warsaw is the only place in the world that not only has a rock band called Morris Taper and the Reamers but also thousands of residents who appreciate the joking reference to an artificial hip joint design — the Morse taper — and the devices used to prepare bones for an implant. And where else would a golf competition between teams from major employers be known as the Lesser Trochanter Open, a reference to a bony protrusion on the hip where leg muscles are attached?

"I'm always amused at how many people from this small town I run into in places like Seoul or San Francisco at international medical meetings," said Ron Davis, president of Zimmer.

In all, the orthopedics manufacturers employ more than 4,000 people in Warsaw and the surrounding region. Hundreds of them are employed by a host of specialty manufacturers that



Steve Kagan for The New York

Lingga Tanamal, an engineer at Zimmer, the market leader, holds an artificial joint.

have grown up to serve the big orthopedics companies. Othy Inc., for instance, processes components for the manufacturers and many of their out-of-town rivals on its computer-controlled machine tools and makes specialty screw drivers, mallets, orthopedic forceps and tools that clean debris from joints before implants are placed in them.

Other suppliers cast metal into shapes approximating implants, which are then shipped to manufacturers for precision work, put the final polish on metal joints made by the larger companies or provide specialized heat treatments. One company, the manufacturing arm of Memphis-based Sofamor Danek Inc., st ed out as a supplier when half was locally owned and known as W saw Orthopedics but now i the m ket leader in the rapidly grow $200 million market for spinal plants.

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anek's evolution is only the latest , that today's employee, supplier partner can be tomorrow's com- tor in the orthopedics business. modern industry was born in when Revra DePuy began mak- wire splints here as an alternative he barrel staves doctors had tradi- ially used to set broken bones. tin O. Zimmer, his first traveling esman, went into business for him- f in 1927 when Mr. DePuy's widow used to give him part ownership of company and to follow his advice add aluminum splints to the prod- line. Mr. Zimmer foresaw that h splints, which do not interfere h X-ray imaging, would quickly come preferred by doctors.

Seven years later, another DePuy esman founded Richards, a Mem- is-based company that is now a sidiary of Britain's Smith & Neph- P.L.C. and one of the industry's ajor players. More recently, Bio- et was formed in 1977 by Dane iller and Jerry Ferguson, two Zim- er executives who felt that compa- had become too bureaucratic as it ew in the years after its 1972 acqui- ion by Bristol-Myers

THE Warsaw companies cooperate locally on a number of social and educational activities. They ovided much of the machinery and sh the town needed to match a 50,000 state grant to build a ma- ine tool complex for high school d vocational college students that specially geared toward training udents for jobs in the industry. ore recently, they provided a large unk of the money to turn more than acres of land donated by Donnelley n the western outskirts of town into a omplex of baseball and soccer fields. ut there is intense rivalry too.

"There aren't enough restaurants town so that you are bound to bump to the others," said Todd Smith, irector of research at DePuy. "We ave to converse very quietly to keep ur secrets."

Mayor Plank is well aware of such inor drawbacks and a few larger nes, such as the lack of commercial ir service to accommodate the thou- ands of surgeons, technical experts nd sales people the companies bring o town each year for meetings. "This ommunity isn't just where they nake products," Mayor Plank said. 'It's also their sales room."

Unless industry trends change, the companies may find it increasingly difficult to be as generous to Warsaw as they have been in the past. The orthopedics industry has run into slower growth than it has been accustomed to as health maintenance organizations and hospital administrators strive to drive down spending. The inability of the overburdened Food and Drug Administration to act quickly on petitions to approve new medical devices is also hurting.

Growth rates for both hip and knee replacements, the biggest chunk of the market, fell sharply in 1993. The increase in the number of operations did not keep up with the trend projected from the aging of the population, price increases were smaller than in the past and the mix shifted toward less expensive products, according to industry analysts.

Joel Zimmerman, who follows the industry for Lehman Brothers, estimated that domestic sales of hips and knees rose just 5.7 percent in 1993, to $1.62 billion, compared with a 15.4 percent increase in 1992. Nor does he see any reason for traditional double-digit growth rates to resume soon. In fact, although he expects the number of artificial knees and hips implanted this year to inch up from 344,000 to 355,000, he projects a drop back to the 344,000 level in 1995. In a truly strict cost control environment, he figures, the number of knee replacements could fall by 25 percent and hip replacements by 10 percent.

COMPANY executives here say the slowdown in unit sales is harder to explain than the cost pressures. Longer-lasting products, growing conservatism among surgeons and uncertainty about insurance coverage may all be factors.

"We are learning to speak the language of managed care," said William Tidmore, president of DePuy. "We were always aware of things like how long it took to put one of our products in a patient and how quickly they could be released from a hospital, but now we are more concerned about documenting the costs."

The one thing the executives agree on is that there is more danger than hope on the horizon in Washington. Congress has been considering proposals that could cap spending on orthopedic devices along with drugs and other medical treatments. The proposals also include various types of Government review and management agencies that the companies say would stifle innovation.

The company executives here say such inhibitions on research and development would come at a crucial time in the industry's history. While further improvements in materials are expected, several of the companies are betting that the next big breakthroughs will come from using biological agents to stimulate restoration of human bones, either alone or in connection with mechanical implants.

The direction of orthopedics research and product development could also be thrown into turmoil if pharmaceutical companies can successfully develop drugs to prevent osteoporosis or osteoarthritis, diseases that account for a large percentage of bone replacement surgery in older people.

To defend their point of view, the executives have been relying largely on the lobbying expertise of the Health Equipment Manufacturers Association in Washington or of their parent companies.

Among those most affected by the market-driven changes already under way are Zimmer and Howmedica, a Pfizer Inc. subsidiary based in New Jersey that is the industry's second-largest company. Analysts believe both are losing market share. Zimmer has cut its workforce here by 350, to 1,900, since 1992, partly by layoffs that were the first ever in Warsaw by one of the major orthopedics companies.

But even Biomet, which has been gaining on its competitors, has been hurt by failing to keep up with Wall Street's expectations — its stock topped $23 in early 1992 but then fell in stages to a low of $8.875 in September 1993, before edging back up. It closed Friday at $11.875.

"A lot of my neighbors bought near $20 so you can bet I hear about it," said Mr. Miller, the company's chief executive. ■

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[redacted]h Risk

Amid Lax Regulation, Medical Devices Flood A Vulnerable Market

Industry Protests as the FDA Now Attempts to Reverse Decades of Laissez Faire

'Using Public as Guinea Pigs'

3/24/92

By BRUCE INGERSOLL

Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON—Soon after Orcolon, a gel used in eye surgery, was approved by federal medical-device regulators in March 1991, things started going awry.

By May, doctors were alerting the manufacturer, Optical Radiation Corp., to adverse reactions to the product, including a potentially blinding buildup of eye pressure in patients. In July a Michigan cataract specialist, blaming Orcolon for two cases of blindness, wrote the company: "It is hard for me to believe that you continue to advertise and sell this product." Not until October, after 33 patients who were treated with Orcolon had undergone surgery to save their eyes, did the company take the product off the market—under belated pressure from the Food and Drug Administration. The company denies any wrongdoing and blames the problem on an undetected contaminant.

Now a criminal investigation is under way into why Orcolon was approved in the first place despite a flurry of red flags, including clinical evidence that it could cause elevated eye pressure, according to people familiar with the probe. An FDA investigative team is preparing a possible criminal case for the Justice Department to prosecute, while a House oversight panel is about to launch a systematic review of the way the FDA approves medical devices.

Medical Devices:

Who's Checking?

First of two articles

FDA Commissioner David Kessler, for one, fears that past lax regulation by the agency's Center for Devices and Radiological Health may yet boomerang into a scandal. "I'm not sure evil lurks here," he says. "If there are integrity problems, I'll deal with them."

Little Oversight

Since becoming commissioner in 1990, Dr. Kessler has been trying to reverse a decade of laissez-faire policies, stepping up enforcement and insisting on more safety tests before high-risk devices are cleared for the market. Manufacturers complain the agency is impeding the development of medical technology urgently needed by patients. "It's stultifying our industry," says Frank Wilton, chairman of Ethox Corp., a Buffalo, N.Y., device maker.

The Kessler approach is a jolting change from the regulatory minimalism of the past. The Center for Devices—in part because of a lack of funds and staff, in part because of the philosophical bent of its leaders—has disregarded entire sections of the 1976 medical device law it was supposed to carry out.

The upshot: Of 60,000 devices on the market today, from breast implants to lasers, the vast majority received the same cursory review as the innocuous tongue depressor, according to government auditors. Last year an advisory panel, headed by former FDA Commissioner Charles Edwards, took a look at the devices center's operations and warned that "a crisis is surely impending."

Critics contend the agency's tilt toward accommodating industry has taken too much of a toll. A 1989 congressional audit found that of 53,000 reports on adverse incidents filed with the FDA by device manufacturers, 55% involved serious injuries to patients and others; 3% involved deaths. Malfunctioning devices were to blame for 42% of the cases. Alarm failures on infant-breathing monitors resulted in the deaths of four babies. One device alone—the fracture-prone Bjork-Shiley heart valve—is blamed for more than 300 deaths. FDA officials are looking into at least 15 fatal cases of anaphylactic shock apparently triggered by latex tips on enema devices.

Problem Devices

At a hearing tomorrow, members of the House Energy and Commerce Committee's oversight panel will question FDA officials about a series of deaths in 1986 and 1987 involving Theratronics International Ltd., a company owned by the Canadian government. Three cancer patients—two in Tyler, Texas, and one in Yakima, Wash.—died from overdoses of radiation because of glitches in Theratronics-made linear accelerators, according to a 1991 FDA inspection report. And a Columbus, Ind., patient was crushed to death when the two-ton treatment head on the company's Eldorado cobalt-therapy device broke loose and fell on her.

Despite the deaths, the FDA's regulatory response has been slow and largely ineffectual. It wasn't until June 1990 that the FDA wrung a pledge from the company to correct the flaw on 70 Eldorado units throughout the U.S. And it wasn't until February 1991 that FDA inspectors got around to inspecting, for the first time, the company's Carrollton, Texas, facility. What did they uncover? Files on another Eldorado-crushing death, this time in China; thirty-six deviations from good manufacturing practices; more than 300 complaints about problems, many "life-threatening"; plus repeated failures by Theratronics to correct such hazards.

Panel Chairman John Dingell, a Michigan Democrat, calls the inspection and a

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law. So far, it has called for safety data on only eight categories, and belatedly at that. Breast-implant makers, for example, didn't have to submit data until last year, two decades after questions first arose about the safety of silicone gel.

Higher Priorities

"It's been a scandal for years," says Robert Adler, associate professor of legal studies at the University of North Carolina Business School. "They basically used the public as guinea pigs for the pre-1976 products," he charges. Mr. Villforth explains that pre-1976 devices "didn't seem to have the urgency of some of the newer things coming on the market. They appeared to be doing reasonably well."

Every time lawmakers demanded an explanation for the agency's inaction, it cited a lack of staff and higher priorities. It also blamed the 1976 law itself for making the standard-setting process too ponderous. But today officials are more forthright about their stance on mandatory standards.

"We didn't think it was a good idea," says Mr. Villforth. "How's that for arrogance?"

Even though Congress streamlined the standard-setting procedures in 1990, the FDA still limits itself to offering technical advice to industry standards groups—and trusting manufacturers to honor voluntary standards. This approach doesn't necessarily keep hazardous devices off the market. From 1983 through 1988, according to a GAO study, 74% of all recalls involved devices for which the agency failed to set mandatory standards.

The lack of performance standards left FDA officials essentially one criterion—something called "substantial equivalence"—for evaluating most devices. For years, their policy has been to let manufacturers introduce a new device merely on the strength of assurances that it has the same intended use and substantially the same technical attributes as a pre-1976 medium-risk device. More than 98% of all device submissions pass muster. Says a former FDA attorney derisively: "If you compared a device to a horse, you could get a substantial-equivalence decision."

The regulatory loophole has been enlarged to accommodate follow-on products, even technological breakthroughs. "If we didn't do it, we'd be slowing up products coming to market," says Mr. Benson.

Push for Surveillance

Two years ago, members of Congress who oversee the FDA gave up trying to prod the agency into writing performance standards and thoroughly reviewing product safety. For one thing, neither the Bush administration nor Congress was willing, given the budget deficit, to underwrite the cost. For another, the mindset of senior device regulators was still decidedly deregulatory. So lawmakers voted to de-emphasize pre-market review in favor of much stronger post-market surveillance.

The 1990 law requires hospitals, nursing homes and outpatient clinics—and eventually device distributors—to report deaths and serious injuries and illnesses involving medical devices, just as manufacturers have had to do since 1984. The new requirements, by all accounts, will double the number of these reports to 50,000 a year—far more than the agency can evaluate.

There's plenty of evidence the reports will never be the early-warning system for detecting problems Congress envisioned. Underreporting, for one thing, is rampant. The Public Citizen Health Research Group, a consumer group, found that 35 manufacturers neglected to report hundreds of malfunctions, many of which resulted in deaths and injuries. In another case, the maker of an insulin-infusion pump received almost 1,500 complaints, but reported only 15 to the FDA.

The Theratronics case further calls into question heavy reliance on post-market surveillance. FDA investigators, in going through the files of Theratronics, discovered the company had failed to report 21 recalls and safety alerts as well as the 1987 death of a Chinese patient, according to FDA documents. In that incident, the automatic couch on the Eldorado malfunctioned, rising up and crushing the patient against the large treatment head. What's more, the company didn't report an identical couch malfunction in 1990—or take any corrective action.

The Education Regulator

The FDA has long shown a reluctance to use its enforcement powers. It has banned only one product—synthetic hair implants in 1983—and prosecuted only a half-dozen manufacturers on criminal charges since 1976. "Maybe we've been a little lax about enforcement," says Mr. Villforth.

His successor, Mr. Benson, advocates education programs to reduce errors by device users. "If Kessler is an enforcement zealot, I'm an education zealot," he asserts. "To me, enforcement isn't the mission of the agency. It's public health. It's [changing] the behavior of the docs, the nurses and other users."

In 1990, as part of the shift from pre-market review to post-market surveillance, Congress also gave the agency new enforcement powers, including the power to impose fines. Under Dr. Kessler, the FDA seized 67 defective products in fiscal 1991, up 109% from the previous year. It also obtained court injunctions against seven companies, up from four.

Industry has had trouble adjusting to the more-aggressive regulation. "It's almost an us-versus-them policeman's mentality," complains Alan Magazine, president of the Health Industry Manufacturers Association, which represents 300 device makers nationwide. "In the past, it was a more cooperative relationship."

The industry is unhappy about the closer scrutiny being given to new high-risk devices. The number of product approvals fell 43% to 27 in fiscal 1991. The lag has reached the point that it is thwarting would-be entrepreneurs and stifling technological development, manufacturers say.

"If our innovation is slower than our [foreign] competitors' we've very clearly got a problem," says Burton Dole, chairman of Puritan Bennett Corp., a Kansas City, Mo., maker of respiratory equipment. Adds Mr. Magazine: "It's just as important to public health to get [illegible] on the market as it is to get [illegible] products off the market."

But Dr. [illegible] promises [illegible] scrutiny won't go away. "We [illegible] bly cautious, particularly about those devices that are implanted in human bodies, or whose [illegible] death," he [illegible]

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[redacted] indirect risk [redacted] would go unde[redacted] lethal.

The agency's Dr. Alpert says the fact that a device is simple doesn't necessarily mean it is benign; everything depends on its "intended use." She dismisses endorsements from doctors and patients – which, she says, many device makers trot out – as anecdotal evidence that is insufficient to make a scientific case. "Reporting doesn't do it – data does," she says.

In 1992, only 12 medical devices were given FDA premarket approval, including heart pacemakers, lenses that are implanted into the eye after cataract surgery and devices for smashing kidney stones. Of the simple, noninvasive pad, "I've never seen a product like this held off the market," says John Isaacs, a gynecologist in Evanston, Ill., who is the author of a textbook on breast disease.

But the FDA says the Sensor Pad needs to be scrutinized because it isn't "substantially equivalent" to a product already on the market, a legal requirement for quick approval of simple devices. The Wrights argue that the pad is substantially equivalent to soap and water, a mixture the medical community has long recommended to reduce friction in breast self-examination.

To obtain premarket approval, the FDA said, Inventive Products would have to conduct exhaustive clinical tests on women, comparing the number of breast-cancer cases detected through self-examination with and without the Sensor Pad. Such tests, Mr. Wright says, would require a huge sample – a minimum of 82,000 women – to produce statistically meaningful results. An FDA spokeswoman disputes that figure. "We want to be as reasonable as we can," she says. "The number will be much less than that."

Mr. Wright says he has already done two trials with simulated breast models, which he claims yield more accurate results. In the first, women examined the artificial breasts for lumps using both the pad and their bare hands. In the second, they used both those methods and also a third method – soap and water on their hands. The tests showed that the pad enhanced sensitivity and resulted in increased lump detection, Mr. Wright says.

The FDA rejected his trials as insufficient. The prospect of starting over with the lengthy, expensive tests the FDA demanded pushed the Wrights to change their course. Because they never considered the pad to be a medical device as defined by federal law, they decided in 1988 to [redacted] the product [redacted] to [redacted] The [redacted] figured [redacted] either would recognize its lack of jurisdiction or take Inventive Products to court and force the issue.

[redacted] Wright

Over 15 months, the Wrights sold 250,000 pads to some 200 hospitals. But in April 1989, federal agents raided the company's Decatur plant and a number of hospitals and confiscated the pads.

The action came one day after Earl Wright was named a finalist in the Intellectual Property Owners Foundation's inventor-of-the-year contest for his "touch-enhancing device."

Grant Wright challenged the FDA's claim to jurisdiction over the pad. But in 1990, a U.S. district court in Danville, Ill., ruled for the FDA. Mr. Wright appealed, and two years later an appellate court in Chicago upheld the ruling. At that point, Inventive Products told the FDA it had ceased marketing the pad.

But Mr. Wright didn't give up. In March 1992, he filed an ethics complaint with the FDA's integrity office against some agency officials after learning that they had met with a minority shareholder of the company without his knowledge. After he filed the complaint, he says, the FDA turned hostile. At a meeting in Washington in August 1992 to discuss requirements for premarket approval, he says, an FDA lawyer – flanked by 10 other agency officials and a Justice Department lawyer – "told us we'd never get our product to market."

An agency spokeswoman says it is doubtful such a remark was made. "We have gone out of our way to show the Wrights how to get their product marketed. Such a comment doesn't make sense," she says.

Mr. Wright promptly fired off letters of complaint about the meeting to the FDA and to Rep. John Dingell of Michigan, who is known for flailing the FDA for its missteps. More letters flew back and forth. An FDA integrity officer wrote that the FDA was acting in good faith. Mr. Wright responded by demanding an investigation of the FDA lawyer who attended the August meeting. A couple of days later, his Washington lawyer sent a seven-page letter to a Dingell staffer, accusing the FDA of "hounding" Inventive Products.

Four months later, the Wrights received notice from an FDA compliance officer that the agency was investigating them for possible violations of federal law for selling the pad in 1990-91. Mr. Grant says he has received no word about the investigation since an FDA administrative hearing in Chicago last June. But, he says, he has gotten the message: "If you squawk, they will slap you around." The FDA denies taking any retaliatory actions.

Meanwhile, members of the medical community continue to support the Sensor Pad. Dr. Withers, the surgeon at Maui Clinic, says the pad has twice enabled him to feel otherwise undetectable lumps. He scoffs at the idea that using it might give women a false sense of security, one of the FDA's main concerns. "There is no question that the Sensor Pad increases my tactile ability," he says. "It makes it 100% easier."

Gale Katterhagen, medical director of the cancer center at St. Joseph Medical Center in Burbank, Calif., says tests he conducted for Inventive Products several years ago indicated that women who used the pad were 22% more likely to perform monthly breast exams. "This device is harmless," Dr. Katterhagen says.

Women who use the pad swear by it. Ms. Richardson, a 43-year-old Decatur resident, doubts that she would have found two small lumps without the pad. She had a double mastectomy. "It probably saved my life," she says, adding that she gave one to her 19-year-old daughter.

Mary Gorman, a 55-year-old writer in Washington, is certain the pad saved her breast. "I found my cancer before it was detectable on a mammogram," she says. Her surgeon, Katherine Alley, says the device may have saved Ms. Gorman's life. Considering the lethality of breast cancer, Dr. Alley says, "it is just ridiculous" to keep the pad off the market.

Potential demand appears to be huge. When a Pittsburgh hospital offered on local TV in 1990 to send out free samples, it was flooded with 36,000 calls and letters.

For all that, the FDA's Dr. Alpert believes that Inventive Products is largely responsible for the delays it has encountered. "There are lots of different kinds of trials they could do to show this is effective," she says. "It doesn't have to be years and years."

The elder Mr. Wright has managed to commercialize the Sensor Pad's antifriction technology for a much smaller market. He has built the Slipp, a nylon and plastic sheet used in hospitals to transfer patients from a gurney to a bed. About 500 have been sold.

But his son spends much of his time in his nearly empty headquarters explaining to doctors why he can't send them samples of the Sensor Pad. Last year, he laid off his own brother, reducing his work force to himself and his secretary from a peak of 28 six years ago. "We're at the point of surrender," he says.

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MEDICAL DEVICE REGULATION: THE FDA'S NEGLECTED CHILD

An Oversight Report on FDA Implementation of the Medical Device Amendments of 1976

REPORT

OF THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

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II. SUMMARY OF FINDINGS, CONCLUSIONS, AND RECOMMENDATIONS

1. Through negligence, or by intention, the FDA has failed to implement major provisions of the medical device amendments to the Food, Drug, and Cosmetic Act:

(a) The agency has lost control of the medical device classification process, failing to complete in 6 years major tasks for which Congress allocated 1 year.

(b) The agency has not even begun to develop standards to assure the safe, effective performance of class II devices.

(c) The agency has not required manufacturers of "old" class III devices to submit premarket approval applications.

(d) The agency has adopted no valid, reliable adverse experience reporting system to inform the agency of device-related deaths, injuries, or device defects.

(e) The agency has used its significant new authority to notify professionals and users of devices of risks of harm a mere three times in 6 years, and it has used its authority to order repair, replacement, or refund but once.

2. The FDA is relying almost exclusively on "General Controls" to regulate devices when it previously determined that such general controls were inadequate.

3. As a consequence, the FDA is not equipped and, therefore, is unable to assure the American public that many medical devices currently on the market—and relied upon to treat disease and to sustain life—are safe and effective.

4. By failing to "restrict" devices in order to address problems caused through their misuse by inappropriately trained persons or in poorly equipped facilities, the FDA has failed to deal with the most frequent source of device-related injuries.

5. The FDA seriously compromised the credibility of its law enforcement deterrent when, having found clear violations of law, it failed to recommend meaningful prosecutive action promptly and vigorously.

(a) In the case involving Baxter-Travenol, the agency failed to recommend prosecution for the intentional submission of false information in a report required to be submitted to the Government.

(b) In the cases involving Bausch & Lomb and Wesley-Jessen, the agency, after making repeated, unequivocal public announcements of its position, delayed recommending prosecution against two companies, which openly defied the agency's admonitions not to market certain bifocal soft contact lenses without prior FDA approval. The remainder of the industry sought such approval and was thereby greatly prejudiced by its adherence to governmental pronouncements that apparently did not represent a position the Government was prepared to enforce.

6. The FDA's delay in down-classifying certain soft contact lens materials out of class III has perpetuated the monopoly profits of the few firms that hold FDA approval to market these materials. It has prevented others from entering the market and competing on price.

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And it has, therefore, allowed prices for these devices to remain artificially high.

7. Although the agency recognizes that tampon absorbency is related to the risk of toxic shock syndrome, the FDA has established no performance standards for tampons (a class II device). Consumers are therefore unable, except through their own experimentation, to compare tampon brands on the basis of absorbency.

LEGISLATIVE RECOMMENDATIONS

As Chairman Dingell made clear at the commencement of the July 16 oversight hearing, legislative modifications will not substitute for full and faithful execution of the law. Indeed, the subcommittee uncovered no evidence that calls into question the essential soundness of the measured regulatory system that lies at the core of the device amendments. What was revealed instead was an astounding lack of action on the part of the Federal agency charged with implementing that system and thereby protecting the public health. To say that the subcommittee recommends that the device amendments be implemented as written would be too mild. The subcommittee, as elected representatives of the American people, demands it.

This is not to say that specific, narrowly crafted legislative proposals aimed at streamlining certain aspects of the regulatory process would be inappropriate. But the subcommittee is concerned that any proposal to streamline a process that has not even begun may be misdirected. The system must be tried before areas for improvement can be identified. Despite these misgivings, the subcommittee does believe that congressional attention may legitimately be directed to the problem presented by the agency's classification of most medical devices into class II, requiring the promulgation of over 1,000 separate performance standards. Accomplishment of that task, according to any procedure no matter how streamlined, is a practical impossibility. The subcommittee, therefore, recommends that consideration be given to alternatives that recognize that although devices placed into class II may pose significant risks to health, with respect to some devices those risks may be addressed by a species of controls less comprehensive than the mandatory performance standards now required by section 514.[5]

III. THE DEVICE AMENDMENTS—AN OVERVIEW

A. DEVICE CLASSIFICATION—SECTION 513

The amendments create a three-tiered classification system of ascending stringency into which all medical devices must fit. Class I is reserved for the least risk-laden devices. Regulatory controls for these devices are general in scope and do not, as a rule, involve device-specific requirements. Class II is reserved for devices to which the general controls apply, but which need more to assure their safety and efficacy. Performance standards establishing levels of device functioning, labeling and other features are necessary. Class III is reserved

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[5] This recommendation is discussed more fully at pp. 17–18 infra.

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already marketed device is not an assurance of safety and efficacy. It is simply a recognition that a newly introduced device poses risks and benefits not materially different from an already marketed device, and that it may, therefore, be regulated in the same fashion to assure its safety and efficacy. To the extent the device to which the newly introduced device is equivalent poses risks, or lacks efficacy, so also will the new device pose risks or lack efficacy. It is regrettable that this crude mechanism—never intended as a substitute for measured, direct regulatory requirements—has come to be relied upon for so much in the regulatory system.

Given that the 510(k) process—by default—has become a more important regulatory tool than Congress envisioned, two conclusions are apparent. First, until the agency has taken serious steps to implement the statutorily mandated three-tiered regulatory system created to assure that marketed devices are safe and effective, any attempt to weaken the 510(k) process—especially to facilitate entry of class II and class III substantially equivalent devices into the market—should be resisted. This would include attempts to reduce the burden in terms of the amount of information now called for in the agency's regulations governing the premarket notification process.[128] This conclusion is by no means an endorsement of the use of the 510(k) process as a substitute for class II and III regulatory controls. It simply recognizes that no matter how desirable or necessary, these controls cannot be fully implemented to provide protection immediately. Something must continue to fill the gap while the agency begins to put the mandated controls in place.

Second, the agency must insist, through all available means, that the information provided in 510(k) submissions is accurate and complete. When manufacturers supply inaccurate or false information, and the agency learns of this, it must take pains to assure that its response reinforces the integrity of the 510(k) process. Unfortunately, this has not always occurred. In the matter involving Baxter Travenol Laboratories, discussed immediately following, the agency's limp response to the intentional submission of false information jeopardized the integrity of the 510(k) process by signaling the industry that the agency lacks the backbone to attack abusers vigorously.

VII. FOUR CASE STUDIES OF REGULATORY TIMIDITY

A. VOLUMETRIC PUMP CASSETTE

The IMED Corp. is a relatively small device manufacturing firm that has profitably marketed a medical device since 1974 which regulates the flow of intravenous fluid from its source to the patient. Called a volumetric infusion pump, this device represents a substatnial improvement in the precision of intravenous administration. The pump

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[128] Although the statute allows 90 days for the agency to review 510(k) submissions, the agency has been processing submission in a time frame averaging 40 day. (BMD Submission retained in the Subcommittee files). The Harris Survey, referred to in section IX, infra, asked respondents about their experience with, and to rate the reasonableness of, the 510(k) process. 44 percent of respondents had never filed a 510(k); 52 percent had filed (table 5–9). Despite the fact that many had no experience, all respondents were asked to rate the reasonableness of the 510(k) requirement. 45 percent felt it was either very or somewhat reasonable; 41 percent felt it was very or somewhat unreasonable (table 6–6). This relationship—a slight plurality believing it to be more than less reasonable—was carried over into the two subsamples of those that had and had not filed a 510(k).

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accommodates a disposable plastic cassette, engineered to fit into a hollow receptacle, that connects to the line of flow and regulates it by means of a rotating valve that opens and closes. The cassette must be changed at least every 24 hours.

A good-sized hospital—with 375 beds—has about 35 infusion pumps and it uses approximately 10,000 disposable volumetric pump cassettes each year. The annual national sales of the cassettes are about $50 million.[129] IMED Corp. manufactures the most widely used infusion pump. It, naturally, also sells a large number of volumetric pump cassettes to fit its pump. Another infusion pump is manufactured by Baxter Travenol Laboratories, Inc., but it does not use a disposable cassette.

IMED's pump cassette business proved exceedingly attractive to Baxter Travenol—the world's largest manufacturer of intravenous solutions with assets over $800 million, and 1980 sales over $1.3 billion. It decided that the disposable volumetric pump cassette business was lucrative enough to justify duplicating IMED's cassette, notifying the FDA of its intention to market this substantially equivalent device, and marketing it under Travenol's name to fit the IMED pump. Travenol's cassette is now on the market competing with IMED's; IMED is suing Travenol for patent infringement.[130]

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[129] Recent press accounts report that IMED is being bought by Warner-Lambert for $465 million. Remarks attributed to Warner-Lambert's president forecast that, by 1990, the disposable cassette market may approach $700 million. MDDI Reports, Vol. 8, No. 29, July 19, 1982, p. 9.

[130] *IMED Corporation v. Travenol Laboratories*, Civ. Action No. 81–C–3155, N.D. Ill. The effect of a finding of substantial equivalence upon the rights and liabilities of parties under the patent laws presents intriguing questions: To what extent can an FDA finding of substantial equivalence be used as evidence of patent infringement? Might such a finding be prima facie evidence of infringement? Under the patent laws the courts have developed a doctrine of equivalents which prevents a party from making only insignificant changes to another's patented device and thereby avoiding liability for infringement. The Supreme Court has ruled that:

"One thing is substantially the same as another if it performs substantially the same function in substantially the same way to obtain substantially the same result. . . . Authorities concur that the substantial equivalent of a thing, in the sense of the patent law, is the same as the thing itself; so that if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form or shape [citation omitted]." *Machine Co. v. Murphy*, 97 U.S. 120, 125 (1877). See *Graver Tank & Mfg. Co. v. Linde Air Products*, 339 U.S. 605 (1950).

This superficial congruence in legal standards, however, may not withstand analysis. The substantial equivalent of a thing, for purposes of the patent laws, may well not be the same as its substantial equivalent for purposes of the medical device law. What makes this distinction in standards with similar-sounding names plausible is the wide discretion vested by Congress in the FDA to employ a flexible interpretation of substantial equivalence in administering sections 513(f)(1) and 510(k) of the device amendments:

"The term substantially equivalent is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purpose as marketed products. The committee believes the term should be construed narrowly where necessary to assure the safety and effectiveness of the device but not so narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness. Thus, differences between new and marketed devices in materials, design, or energy source, for example, would have a bearing on the adequacy of information as to a new device's safety and effectiveness, and such devices should be automatically classified into class III. On the other hand, copies of devices marketed prior to enactment, or devices whose variations are immaterial to safety and effectiveness would not necessarily fall under the automatic classification scheme." House Report, supra, note 3, pp. 36–37.

Given this legislative history, which indicates that where differences relate to the safety or efficacy of a device, substantial equivalence should be construed narrowly (and vice versa), it would, therefore, appear that in any given case, the concept of substantial equivalence for medical devices may be more or less expansive than for purposes of patent infringement.

The flexibility of the substantial equivalence standard for purposes of medical devices is confirmed by the fact that the FDA has not specified any meaning for the term in its regulations [see 21 CFR, secs. 807.81(a), 807.87(h)], it has not clearly indicated the kind of data needed to support a manufacturer's assertion of substantial equivalence, and it has reserved the discretion to request any additional information regarding the device that it deems necessary to decide whether or not a device is substantially equivalent to another [sec. 807.87 (f) and (h)]. Finally, when the agency determines that a device is substantially equivalent to another, the reasons for its finding are not revealed to the public. (Under certain circumstances the manufacturer's submission will be made public, section 807.95.) This, it would seem, would make it difficult to argue that the agency's determination has any particular relevance in an infringement action.

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Depositions taken in the *IMED* v. *Travenol* patent suit revealed many of Travenol's activities in developing and marketing its look-alike disposable cassette. Of special significance is the fact that Travenol lied to the Food and Drug Administration in submitting its 510(k) prior to marketing the cassette. Investigation also revealed that FDA was aware that the Travenol cassette had been tested by two independent university hospital laboratories and had been found to be defective. The agency dismissed this evidence as inconsequential and was unable at the July hearings to assure the public that the device was safe.

The depositions in the patent infringement suit establish that Travenol wanted to commence marketing its disposable cassette by July 1, 1980,[131] and its engineers and marketing personnel knew that one of the required premarketing steps was to get the necessary clearance from FDA. Accordingly, on March 27, 1980, Travenol sent FDA a formal 510(k) notification stating that it was providing 90 days prior notice of its intention to market the cassette. Travenol stated that its cassette was substantially equivalent to the cassette marketed by IMED. Travenol also stated that the equivalency of the products was supported by:

1. Photograph of IMED C-924 Accusett.
2. Photograph of Travenol 2C1020 Volumetric Pump Cassette.
3. Labeling accompanying IMED C-924 Accusett.
4. Draft labeling for Travenol 2C1020 Volumetric Pump Cassette.[132]

In fact, at the time of this 510(k) notification, no Travenol cassette existed. The second photograph submitted with the 510(k), which was labeled as the Travenol device, was actually a second photo of the IMED cassette. One of Travenol's employees was instructed to shave off a strip of its plastic body, and the company's regulatory affairs administrator knowingly and falsely labeled the device as the Travenol 2C1020 Volumetric Pump Cassette.[133] FDA duly reviewed the March 27, 1980 Travenol 510(k) submission, noted nothing extraordinary, made a telephone request for clarifying information on the materials used, and approved it on May 8, 1980.

Travenol was not ready to market the cassette by July 1, as originally planned. Significantly, in November/December 1980, when Travenol started biding on various hospitals' invitations to supply cassettes, it learned that the hospital biomedical director at the University of Arkansas had tested Travenol's cassettes and found that they leaked fluid into the intravenous line when the valve was supposedly closed.[134] This finding was corroborated by the results of a similar test at the University of Nebraska.[135] The leaking was substantial; the range of uncontrollable flow of 56–103 ml. per hour equalled normal dosage flow ranges depending on the drug used.[136]

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[131] Deposition of Michael P. DeFrank, June 29, 1981, at p. 20. Mr. DeFrank was program manager of Travenol, responsible for development of all of Travenol's disposable devices for intravenous administration (Dep. at p. 10).

[132] Hearings, supra, note 3, pp. 234–243.

[133] DeFrank deposition at pp. 203–11.

[134] Letter, Nov. 5, 1980, from Lawrence A. Robinson, M.S., Pharm. D., University of Arkansas for Medical Sciences, to Thomas Nickel, Product Manager, Infusion Pumps, Travenol Laboratories, Inc. Hearings, supra, note 3, pp. 224–26.

[135] Memorandum, Dec. 17, 1980, from Larry Fennigkoh, CCE, Director, Biomedical Instrumentation, University of Nebraska Medical Center. Hearings, supra, note 3, pp. 219–23.

[136] Id., pp. 99–100.

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FDA first learned that Travenol had lied in its March 1980 510(k) notification on August 6, 1981, when IMED's lawyer presented FDA's Chicago field office with the incriminating deposition of one of Travenol's responsible officials and the two hospital clinical evaluations. Just 9 work days later, Travenol sent FDA a supplement to 510(k) notification in which it stated that it wanted to update our file by supplying a photo of a currently marketed Travenol cassette. Travenol also stated: "Attachment 2 of the original * * * submission dated March 27, 1980, included a photograph of a prototype 2C1020 set which was an IMED cassette modified to reflect Travenol design."

Based on IMED's allegations, and on Travenol's virtually contemporaneous confirmation, FDA launched an investigation to determine what action was appropriate. The agency addressed two issues: First, did Travenol violate the Food, Drug, and Cosmetic Act (21 U.S.C. 331(q)(2)), or 18 U.S.C. 1001, by filing a false 510(k) in 1980; and second, had Travenol's cassette been further modified from IMED's design, after the filing of the 510(k), to such an extent that FDA's substantially equivalent determination of May 8, 1980 no longer applied.

FDA disposed of the first issue in short order. Various Bureau of Medical Devices officials decided that Travenol's March 1980 510(k) was misleading, at least unethical, and at best deceptive.[137] Yet, they decided Travenol's false statements were immaterial, and therefore not illegal, because the 510(k) depicted the device Travenol intended to market and because FDA's regulations do not require a device to be in existence before a 510(k) notification can be submitted.[138] In interviews with the subcommittee staff, the responsible FDA officials, including the chief counsel's office, explained that if Travenol had correctly stated the facts—that is was intending to market a yet-to-be-developed device and that a photo of a prototype of the device was enclosed—the Bureau of Medical Devices would have approved the 510(k) anyway.[139] Because the falsehood did not affect the Bureau's decision, the argument goes, Travenol's false submission did not violate section 301(q)(2) of the act that prohibits the submission of a required report regarding a device that is false or misleading in any material respect, 21 U.S.C. 331(q)(2). A similar analysis led FDA not to recommend prosecution of Travenol under 18 U.S.C. 1001.

The Bureau's second area of inquiry took more time. If Travenol's currently marketed cassette had been modified since the time of the original 510(k) submission, so that it was no longer substantially equivalent to IMED's, then the Bureau would have grounds to revoke its original 510(k) approval. Throughout October/November 1981, the Bureau attempted to learn whether the Travenol cassette then in use differed from the one the company described in March 1980. The documents obtained, together with staff interviews with the responsible Bureau personnel, reveal that: One, the Bureau contacted Travenol and asked for the changes made in the device since 1980,[140] and two, evaluated the changes and decided that they had not affected either the

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[137] Id., at pp. 244–45.

[138] Id., p. 97, where Commissioner Hayes reiterated this analysis in his testimony.

[139] See letter to Hon. John P. East, U.S. Senator, Dec. 11, 1981. Id., at pp. 227–28.

[140] Memorandum of telephone conversation between Robert S. Kennedy, Ph. D., BMD Associate Director for Device Evaluation, FDA, and Maynard Youngs, assistant general counsel, Travenol Laboratories, Inc., Nov. 9, 1981. Hearings, supra, note 3, p. 229.

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safety and efficacy of the device or its substantial equivalence to the IMED device.[141]

FDA completed its investigation in late November 1981. It decided that no enforcement action of any kind was warranted. The Associate Director of the Bureau of Medical Devices on November 25 wrote to Travenol expressing serious concern that Travenol did not advise FDA of its false statements in its original 510(k) until a year and a half after the fact:

> Additionally, we have learned that at the time of your original submission, a "Travenol" device did not exist other than as an IMED device modified to reflect Travenol's design changes. We believe such omission of information serves to defeat the spirit if not the letter of the law and regulations. Future submissions are to be complete and contain the full and factual information about the status of the device for which the 510(k) notification is being submitted.
>
> In the future, ensure that representation [sic] made to FDA, including photographs of the device, are factual and complete, and contain no ambiguity.[142]

The subcommittee has focused on three issues: First, did an FDA employee improperly contact Travenol in August 1981 and advise it of FDA's discovery of the falsity of Travenol's March 1980 510(k) submission; second, was FDA's decision not to recommend prosecution under 21 U.S.C., 331(q)(2) or 18 U.S.C., 1001 a wise exercise of its enforcement discretion; and third, did the agency's actions adequately protect the public health.

1. Regarding improper contact

The fact that Travenol chose to "update" its 510(k) submission 9 working days after IMED's attorney first called the irregularities to FDA's attention—especially after an 18-month silence—suggests that more than mere coincidence might have been at work. Travenol is headquartered near Chicago, and IMED's attorney had presented the incriminating deposition, as well as the clinical studies, to FDA's Chicago field office.

Subcommittee staff interviewed every current FDA employee involved in FDA's investigation of the Travenol 510(k) and discovered no evidence that any employee improperly contacted Travenol.[143] This conclusion coincides with that arrived at by those in the agency who also sought to ascertain whether any improper contacts occurred. The most likely source of Travenol's August 19, 1981, supplemental submission appears to be the fact that its lawyers attended the Michael DeFrank deposition in late June that, for the first time, revealed Travenol's conduct and the falsity of the submission. Lawyers for both sides advised their clients of the revelations, and both clients apparently decided to contact FDA with the pertinent information in the

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[141] Letter from Maynard, Youngs to Robert S. Kennedy, Nov. 16, 1981, and memorandum from Fernando Villaroel, Ph. D., Director, BMD Division of Gastroenterology-Urology and General Use Devices, FDA, to Robert S. Kennedy, Nov. 25, 1981. Id. at pp. 230–31.

[142] Letter to Thomas D. Nickel, Travenol Laboratories from Robert S. Kennedy, Nov. 25, 1981. Id. at p. 233.

[143] The 12 FDA employees interviewed (in alphabetical order) were: (1) Harry Butts, Director, BMD Division of Compliance Operations; (2) Robert Gatling, Chief, Hospital Devices Unit, BMD Division of Gastroenterology-Urology and General Use Devices; (3) Ann Holt, BMD Associate Director for Compliance; (4) Linda Horton, FDA Deputy Chief Counsel; (5) Robert S. Kennedy, BMD Associate Director for Device Evaluation; (6) Michael Landa, FDA Associate Chief Counsel for Medical Devices; (7) Edward McDonnel, Director, BMD Division of Compliance Practices; (8) Steven Nedelman, Consumer Safety Officer, BMD Compliance Division; (9) Robert Sauer, BMD Executive Officer; (10) Thomas Scarlett, FDA Chief Counsel; (11) Mervin Shumate, FDA Director of Enforcement Policy; and (12) Fernando Villaroel, Director BMD Division of Gastroenterology-Urology and General Use Devices.

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same timeframe.[144] The subcommittee, therefore, finds no factual basis to conclude that any improper contacts occurred.

2. Regarding the FDA's enforcement response

As previously indicated, FDA officials concluded that although Travenol's March 27, 1980, submission was misleading, at least unethical, and at best deceptive, no recommendation to prosecute Travenol was forwarded to the Justice Department. Both available statutory remedies for submission of false statements, 21 U.S.C., sec. 331(q)(2), and 18 U.S.C., sec. 1001, contain materiality elements that must be proved to make out a violation. Attorneys for the agency concluded that Travenol's misconduct was an immaterial falsehood, and therefore, not a violation, first, because officials in BMD stated that their initial decision on substantial equivalence would have been the same if they had known the truth, and, second, because they concluded that the statute and pertinent regulations do not require a device actually to exist before the agency can conclude it is substantially equivalent to a preamendments device. These decisions need to be reviewed in light of the pertinent authorities and, importantly, in light of their effect on the integrity of the entire 510(k) process.

The courts have yet had no opportunity to construe the materiality element in 21 U.S.C., sec. 331(q)(2) which was added to the act by the 1976 device amendments; however, the substantial case law developed in connection with 18 U.S.C., sec. 1001 and its materiality element would undoubtedly be persuasive in construing the former statute. The courts appear to have made clear that it is not necessary that the government actually rely upon or be deceived by a false statement in order for it to be material within the meaning of 18 U.S.C., sec. 1001.[145] The critical issue is whether the false statement is capable of influencing the decision the agency or department must make.[146]

Viewed against these standards, the agency's decision that Travenol's false submission was legally immaterial is excessively timid. FDA's regulations governing the required elements in a 510(k) notification specify that a manufacturer must submit data to support the assertion that the proffered device is substantially equivalent to another device. 21 CFR, sec. 807.87(f). In Travenol's case, misrepresentations to the agency were made to satisfy this requirement. Actually, when its 510(k) notification is fully parsed, Travenol made four false representations to the agency, rather than the single misrepresentation to which the agency's chief counsel referred in testimony.[147] First, the company represented that its volumetric pump cassette (model 2C1020) existed when in fact it did not.[148] Second, the

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[144] Maynard Youngs, assistant general counsel to Travenol, stated to subcommittee staff in an interview on Feb. 23, 1982, that the reason for his company's Aug. 19, 1981 submission was the discovery, by its patent lawyers during the DeFrank deposition, of company employees' misguided conduct in filing the original 510(k).

[145] See *U.S.* v. *Lichenstein*, 610 F.2d 1272 (5th Cir. 1980), cert. denied, 100 C. Ct. 2991 (1980); *U.S.* v. *Jones*, 464 F.2d 1118 (8th Cir. 1972), cert. denied, 409 U.S. 111 (1973); *U.S.* v. *Valdez*, 594 F.2d 725 (9th Cir. 1979); *U.S.* v. *Talkington*, 589 F.2d (9th Cir. 1978); *U.S.* v. *Goldfine*, 538 F.2d 815 (9th Cir. 1976).

[146] *U.S.* v. *Lichenstein*, supra; U.S. Voorhees, 593 F.2d 346 (8th Cir. 1979), cert. denied, 441 U.S. 936 (1979); *Tzantarmus* v. *U.S.*, 402 F.2d 163 (9th Cir. 1968), cert. denied, 394 U.S. 966 (1969); *U.S.* v. *Carrier*, 654 F.2d 559 (9th Cir. 1981); *U.S.* v. *Goldfine*, supra.

[147] Scarlett, hearings, supra, note 3, p. 103. The chief counsel referred only to the submission of the falsely labeled photograph.

[148] Travenol's Mar. 27, 1980 510(k) notification stated, "This pump cassette is substantially equivalent to those marketed by both the IMED Corporation and McGaw Laboratories. * * * The equivalency of the three products is supported by * * *." Id. at p. 234.

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company submitted a photograph, which is represented to be a picture of its cassette, to demonstrate its equivalence to the IMED device. In fact the photographed device was an IMED device with a strip of its plastic body shaved off.[149] Third, the company represented that a list of materials attached to the submission had been used to build its cassette, when in fact the materials had not been used because the cassette had not been built.[150] Finally, when the FDA employee reviewing the Travenol 510(k) submission called the company's Regulatory Affairs Administrator and asked for more information comparing the materials used in the Travenol and IMED devices, the Travenol official stated that "the materials were generally the same" when, again, the device did not exist.[151]

From the face of the Travenol 510(k) submission it is clear the company believed that its representations were responsive to regulatory requirements and were material to FDA's deliberations on substantial equivalency. The submission explicitly stated that the photograph and the other statements representing both that the device existed and had been manufactured from the specified materials were being offered to support the equivalency of the Travenol and IMED devices. When given the chance to correct the misrepresentations 10 days after the submission in a telephone conversation, the responsible company official reiterated the falsehood. The company's assumptions about the importance of its misstatements to FDA's decisionmaking are not surprising; it seems reasonable to believe that FDA's deliberations over the substantial equivalence of a device would be influenced by the data supporting the application and by whether the proffered device was only an engineering concept or was developed, tested to support the instructions for use on its label, in production, and ready for distribution.

What is surprising is how wrong Travenol was in believing that it must adduce evidence to support its assertion that its disposable cassette was substantially equivalent to IMED's. The thrust of Commissioner Hayes' testimony at the hearings was that a simple statement of what it is, what it does is quite sufficient for FDA to decide on substantial equivalence.[152] The Commissioner and others at the agency were particularly concerned that to move against Travenol here would establish the precedent that a device must actually exist before the agency could decide on its equivalence to another device. The Commissioner testified that to require a device actually to exist before making the equivalency decision would be extremely anticompetitive. It would prevent companies from developing prototypes or starting production, presumably because companies would be unwilling to risk the expenditure of capital to develop a new device without knowing in advance whether FDA will stand in the way of its marketing by requiring a full dress demonstration (in a PMA) of its safety and efficacy.[153] The

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[149] DeFrank deposition, pp. 203–11.

[150] Hearings, supra, note 3, p. 238. Due to difficulties encountered in manufacturing the cassette—after the 510(k) had been submitted—Travenol had to make changes in certain items on the list provided to FDA with the 510(k) notification. See letter cited in note 132, supra.

[151] Memorandum of Telephone Conversation between Edward Estrin, biomedical engineer, BMD division of gastroenterology-urology, and general use devices, and Dennis A. Ocwiega, regulatory affairs administrator, Travenol Laboratories, Apr. 7, 1980. Hearings, supra, note 3, p. 232.

[152] Id., p. 97.

[153] Id. If FDA decides that the proffered device is not substantially equivalent, then it is a new device automatically placed in class III and subject to premarket approval.

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FDA wants to retain discretion to deliver a decision on equivalence based, not on what a manufacturer has developed, but on what a manufacturer intends to develop. Based upon its view that a device need not exist before it can be found substantially equivalent, the agency rested its decision that Travenol's misrepresentations were immaterial.[154]

This analysis seems to miss the point, however. Even if the agency may not require it, even if a device's existence is not necessary, statements representing that a device does, in fact, exist are capable of influencing an equivalency decision. As indicated, the four misrepresentations outlined above were directly responsive to FDA regulations covering 510(k) submissions that require the manufacturer to supply data for the agency to consider in deciding whether the proffered device is similar to others. The supportive data required by regulation and supplied by Travenol were false. For the agency to state that it did not rely upon Travenol's assertions because it was immaterial whether the device actually existed injects an element into the pertinent criminal statute that is not there.[155] Even if—unknown to Travenol—FDA was prepared to accept much less by way of support than Travenol had offered, FDA's decision was, at a bare minimum, made easier by the false information Travenol supplied. The subcommittee believes that this information was therefore material within the meaning of 18 U.S.C. 1001, and 21 U.S.C. 331(q)(2), and that if the agency were concerned with the ramifications of its actions—beyond this individual case—it would have recommended prosecution.

Those ramifications are indeed far reaching. As discussed earlier, the 510(k) process is the vehicle by which the vast majority of devices have been allowed onto the market since enactment of the device amendments. Over 17,000 510(k) submissions have been made since 1976, virtually all of which have led to findings of substantial equivalence. This makes it particularly important for 510(k) submissions to be scrupulously accurate and for the agency to take the steps necessary to let manufacturers know the importance the agency attaches to the accuracy of the submissions. FDA's disposition of the Travenol matter sends the opposite signal. In what was, hopefully, a rare opportunity to deal with a manufacturer deliberately falsifying a 510(k) submission and to use this occurrence as an example to let the industry know the importance the agency attaches to the integrity of the 510(k) system, the agency sent a signal of indifference lacking any legal effect. This is an invitation to other firms to follow in Travenol's footsteps.

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[154] A case can be made in support of the agency's flexible policy. Judgments about substantial equivalence are supposed to take account of whether differences between a proffered device and its marketed referent relate to safety and efficacy. See note 130, supra. For some devices, the differences, whether existing or planned, would not relate to safety or efficacy. In these circumstances, there would appear to be no necessity for the device to exist before a 510(k) is filed. In others, where differences could affect safety or efficacy, the existence of a device in final form should be required. The agency can achieve this result by requiring the manufacturer to submit results of tests on the device. However, this flexible policy rests on no explicit foundation in the language of the Device Amendment or FDA's regulations. Section 513(f)(1) of the Device Amendments states that any device not introduced for commercial distribution before enactment of the Amendments "is" a class III device unless, inter alia, it "is" substantially equivalent to a class I or class II device. "Is" was the term used, not "will be." FDA regulations, if anything, speak as if the proffered device must exist. They call for a statement indicating the device is similar to * * * other products of comparable type * * * accompanied by data to support the statement. 21 CFR, part 807.

[155] See cases cited in notes 145–146, supra.

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3. *Regarding the risk to public health*

Equally troubling to the subcommittee was FDA's response to evidence that the Travenol cassette was so defective in design or manufacture that it leaked fluid when its valve was supposedly closed. This evidence, in the form of reports of laboratory tests from the University of Arkansas and the University of Nebraska, was presented to FDA officials at the same time as the incriminating deposition of Travenol's employee. Under questioning, Commissioner Hayes agreed that the level of leakage found to flow through in the studies was within the range of normal dosage—56 to 103 ml. per hour—for certain drugs and that, depending on the drug, the consequences of such an uncontrolled flow through could obviously be serious.[156]

Despite the unambiguous hazard documented by this evidence, prior to the subcommittee's July 1982 hearing the agency ignored it. No other conclusion is possible. FDA was in direct contact with Travenol during this period to inquire about any changes made in the cassette since the original March 1980 510(k) submission, yet no one at the agency asked the company about the defects in the device. In fact, the documents obtained show that the studies were not even mentioned to Travenol.[157] Nor did FDA contact the hospitals where the studies were conducted, or conduct, on its own, any test of the Travenol device then on the market to see if it was defective.[158]

The agency's sole response to this evidence was to conduct a GMP inspection of Travenol's facility and to check the company's complaint files. Because only 21 complaints concerning the device were found, and because the DEN program only had four complaints, the agency assumed the problem was not significant.[159] It made this decision despite the fact that, in general, 60 percent of companies' complaint files are poor or unusable,[160] and that the DEN program, relying totally on voluntary reporting of device problems, vastly understated their incidence.[161]

As a consequence of the agency's failure to follow up on this data—the only evidence of any kind then available to it relating to the safety or efficacy of the Travenol cassette—Victor Zafra, then the agency's Acting Director of the Bureau of Medical Devices, was forced to make a discomforting admission:

> Congressman GORE. Wait a second now. You have got two university hospitals, both of which have tested this device, hooked it up, run fluid through it, and tested it. Both of them say it is life-threatening. Then you come here and tell us in response that you want to reassure us that FDA has looked at it and it doesn't think it is life-threatening.
>
> Do you want to make that statement, Mr. Zafra? Do you want to tell us that you can reassure us that it is not life-threatening?
>
> Mr. ZAFRA. That wasn't the statement I was trying to make.
>
> Congressman GORE. You cannot make that statement, can you? Can you make that statement?
>
> Mr. ZAFRA. No, I don't think we can.[162]

4. *Post-hearing developments*

As a result of the hearings, FDA decided to test the Travenol and IMED cassettes. The agency, first, found no flowthrough characteris-

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[156] Hearings, supra, note 3, pp. 99–100.

[157] See memorandum and letter at Id., pp. 229–31. See testimony at pp. 98–102.

[158] Id., pp. 101–102.

[159] Id., p. 99.

[160] Id., p. 98.

[161] See pp. 26–27, supra.

[162] Hearings, supra, note 3, p. 101.

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tics with the IMED cassette. It next discovered that the Travenol cassette had evolved beyond the model tested and found defective at the Universities of Arkansas and Nebraska, and that two subsequent generations of Travenol cassettes had been developed and marketed. By mid-September 1982 the agency obtained samples of both later generations, both of which were then still in use, and tested them for flow-through characteristics. It found that the second generation model exhibited the defect while the third generation did not. It also learned from Travenol that about 72,000 of the defective original cassettes—tested at the universities—had been marketed and 800,000 of the defective second generation cassettes had been marketed before giving way to the currently marketed third generation. The agency estimated that about 225,000 defective cassettes remained available for use.

The agency thereafter conducted an evaluation of the health hazard presented by the defective cassettes, presumably because it was a product being recalled or considered for recall.[163] The Health Evaluation Committee considered the evidence developed in the FDA laboratory tests and concluded that the use of this device may cause temporary or medically reversible adverse health consequences. The probability of serious adverse health consequences is remote.[164] The committee's choice of this language was not fortuitous; it tracks, verbatim, the agency's definition of the risks warranting designation of a class II recall.[165]

The Evaluation Committee reached its conclusion after consideration of the following: Reports of adverse effects, the likelihood that flow-through would occur in any given situation, and the population at risk if flow-through did occur.[166] First, there had been no reports of complaints or injuries resulting from the defect. Second, the laboratory tests had revealed that uncontrolled flow-through occurs with a defective cassette only when certain conditions are met. The pump governing the intravenous flow must be switched off while the valve in the cassette is rotating. The valve rotates to allow fluid to be sucked into the cassette's chamber, and it rotates again to a different position to allow the fluid to be expelled through the intravenous tubing and into the patient. During each fill/expel cycle of the pump, the valve is actually rotating for only about 1.2 seconds. A typical fill/expel cycle lasts about 20 seconds; so a first approximation of the danger zone during which a flow-through condition could be produced in about 6 percent—1.2 seconds divided by 20 seconds—of the time the pump is in operation. A further condition that must be met before flow-through will occur relates to the actual position of the valve when the pump is switched off during that short danger period—1.2 seconds—when the valve is rotating. The laboratory tests showed that the valve rotates through a total arc of 53 degrees in those 1.2 seconds, but that flow-through occurred only when the rotating valve happened to be within a 7 degree sub-arc when the pump was switched off. This represents about 13 percent of the total space through which the valve rotates in its active 1.2 seconds.

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[163] 21 CFR Part 7.41(a).

[164] The report of the Health Hazard Evaluation Committee is attached hereto at pp. 69–70.

[165] 21 CFR, part 7.3(m)(2).

[166] The step-by-step analysis of the Evaluation Committee, discussed in the text, was communicated to the subcommittee staff at an interview on Nov. 18, 1982.

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Thus, for flowthrough to occur, not only must the valve be rotating—which happens about 6 percent of the time a pump is turned on—but it must be within a particular position range—which represents about 13 percent of the total movement—when the pump is switched off. These conditions combine to produce a risk condition during less than 1 percent of the time (6 percent × 13 percent = .78 percent) that a pump and defective cassette are in use.

That is not the whole calculation of the level of risk involved. The Evaluation Committee also considered the fact that infusion pumps, which are pre-set to administer an entire bottle's worth of fluid at a given flow rate automatically, are rarely turned off by the attending nurse at any time. Pumps are typically switched off only when the bottle is empty and must be changed—but there then is no risk from a flowthrough defect because there is no solution left to flow through. The only other time when pumps may be switched off while fluid remains in the bottle is when the patient needs some supplemental infusion which is to be administered through the same intravenous line that is already plugged into the patient's system—the tubing is designed with a γ-joint to permit this. The Evaluation Committee's judgment was that this supplemental infusion occurred only about 1 percent of all the times that intravenous fluids are administered by automatic pumps. This further diminished the incidence of risk from uncontrolled flowthrough to 1 percent of 1 percent of the time, or to 1 in 10,000.

The third and final risk assessment factor woven into the equation by the Health Hazard Evaluation Committee was the population that would be at risk if an uncontrolled flowthrough occurred. It concluded that that group would principally be critically ill newborn children who were obtaining their sustenance or medication via intravenous administration. Although the consequences here would be alarming indeed, this group of patients only represent, in the Evaluation Committee's judgment, about 1 percent of all patients who might need an I.V. Therefore, the Evaluation Committee's final rough quantitation of the risk of health hazard from uncontrolled flowthrough from a defective Travenol cassette was 1 percent of 1 percent of 1 percent—or one in a million times.

It is instructive that, while small quantitatively, the quality of the hazard was such that the Evaluation Committee chose not to describe it in other terms such as those which would define a class III recall, that is, a situation not likely to cause adverse health consequences. While the risk was remote, it was still significant. This considered decision was a product of the evidence developed in FDA's laboratory tests and the Evaluation Committee's expert clinical judgment as to its significance. Nothing in the Evaluation Committee's analysis suggests it was conducted in other than the routine fashion in which such assessments are frequently made and communicated to the agency's enforcement officials.

Coupled with this assessment of health risk, the agency also obtained documents and information from Travenol that, for the first time, established that the company knew in October 1980—prior to the conduct of the laboratory tests at the Universities of Arkansas and Nebraska—that its cassette then in production was defective. The FDA obtained from Travenol a copy of the laboratory notebook of a

Travenol employee who, on October 9, 1980, conducted two laboratory tests comparing Travenol and IMED cassettes. All of the tested Travenol cassettes allowed air to flow through; none of the IMED cassettes did. Additionally, four of the five tested Travenol cassettes allowed fluid to flow through; none of the IMED cassettes did.[167]

Despite these findings, Travenol released for sale over 2,700 of these defective units on October 27, 1980. Furthermore, the company was not influenced by the reports from Arkansas and Nebraska that it received in November/December 1980 and that confirmed the presence of the flow-through defect. Travenol released an additional 70,000 units for sale between January 1981 and December 1981. The company revised its valve design in an attempt to correct the defect in late 1980—the "second generation" cassette. But it apparently was unwilling to absorb the costs of scrapping or repairing 70,000 defective first generation cassettes—so it sold them knowing that they had problems.

An FDA engineer who reviewed these newly obtained inculpatory documents from Travenol asked the company's general counsel "why Travenol continued to ship cassettes with valves that could exhibit flow-through so long after the valve was redesigned." [168] The company official responded that "theoretical analysis and testing had shown that flow-through would not occur in normal valve positions and that no flow-through complaints had been received from the field." [169] But this was not convincing. In the same conversation, the FDA engineer also asked the Travenol official:

> Why Travenol only pressure tests production cassettes to 8 psig if they are intended for use with pumps which exceed this pressure (some older IMED pumps can generate up to 45 psig opm occlusion). Mr. Youngs said that he did not know. I stated that this is one are [sic] he should explore, since I felt the testing does not make any sense." [170]

Thus, Travenol lied to the FDA; it manufactured a defective cassette; it sold that cassette knowing of its defect; and, apparently, it employed invalid in-house testing procedures that did not assess the cassette's performance under actual operating conditions. The entire record of Travenol's conduct engenders in this subcommittee a sense of affront that is not tempered by the decision of the FDA Hazard Evaluation Committee that the actual chance of serious risk to critically ill newborn children was remote.

It appears, however, that the FDA did not, and does not, share the subcommittee's sentiment. It did not recommend to the Justice Department that the company be prosecuted because the original misstatement in the 510(k) submission was not material. It did not ask the company to recall the 225,000 defective cassettes that the FDA believes still remain available for use. Instead, the agency wrote the company on October 6, 1982, to advise it that the FDA's tests showed what Travenol already knew: That flow-through and valve leakage can occur in these devices.[171] The agency did not ask the company to replace the defective

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[167] The range of flow-through was 15 ml./hr. to 110 ml./hr. This is the same level of magnitude as reported by the two university hospitals.

[168] Memorandum of telephone conversation between George C. Brolick, BMD, FDA and Maynard Youngs, general counsel, Travenol Laboratories, Aug. 31, 1982.

[169] Id.

[170] Id.

[171] Letter to Vernon Loucks, Jr., president, Travenol Laboratories from Ann B. Holt, DVM, Associate Director for Compliance, BMD, Oct. 6, 1982.

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cassettes with the other defect-free ones that Travenol currently sells. Instead:

> In order to preclude the possibility of harm to patients, we request that your firm promptly alert users not to turn off the pumps while the valve is rotating, because to do so may result in flow-through.[172]

The FDA thus permitted Travenol to shift the responsibility for remedying its defective product onto the shoulders of the hospital personnel and individual consumers who use them in their homes.[173]

The agency's October 6 letter invoked section 518 of the device amendments which authorizes the agency to notify health professionals and the public at risk when a device poses an unreasonable risk of substantial harm to the public health and where no more practical means is available * * * to eliminate such risk * * *. In response to FDA's request, on October 20, 1982, Travenol sent letters to its customers stating that it had recently learned there is a remote possibility that a slow rate of solution flow-through may occur when using certain Travenol Volumetric Pump Cassettes. The company stated it was alerting users not to turn off the pump while the valve is rotating. As an alternate procedure, clamp the administration tubing when the power switch is in the off position.[174]

The FDA is now in the process of evaluating how effective Travenol's notification has been. It is not a recall, and, therefore, was not reported in the agency's weekly enforcement report.[175] This undoubtedly saved Travenol a measure of adverse publicity. The agency maintains that although Travenol's action was not termed by FDA a recall, that the FDA's field personnel who are auditing the effectiveness of the company's actions are treating it as if it were a class II recall and as if it were subject to the agency's existing guidelines covering that kind of corrective action.[176] No guidelines or regulations exist which specify manufacturer or agency responsibilities in a section 518 notification program. If the recall guidelines ought to apply, the subcommittee recommends that the agency make them applicable. If different guidelines are necessary, they should be promulgated. Neither the agency nor manufacturers are well served by the resort to remedies that lack a mechanism to govern their operation.

The subcommittee will continue its review of the FDA's activity in this matter.

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[172] Id.

[173] The company advised FDA that 10,731 cassettes had been shipped to home users as of Oct. 25, 1982. Not all of those were defective, however, because some percentage of these were third generation cassettes.

[174] Letter to hospital administrators, from H. J. Nichols, group product manager, Travenol Laboratories, Oct. 20, 1982.

[175] The agency's failure to term this action a recall instead of, or in addition to, a section 518 notification seems inconsistent with other reported actions taken by the FDA in similar situations. The agency's Apr. 7, 1982, enforcement report (p. 4) describes a class II recall of a stationary exercise bicycle with labeling that does not contain adequate directions for use or warnings about the potential risk if the seat attachment bolt and nut are not assembled and secured properly. The June 23, 1982 report (p. 2) lists a class II recall of an infusion pump for anticoagulants where a possibility existed that a primer switch might stick and cause over-infusion if the device is disinfected with certain chemical solutions. The Aug. 11, 1982 report (p. 2) lists a class II recall of a cardioresuscitation system that would not display data on a monitor if the monitor is not properly seated. Each of the three above matters designated as class II recalls involves a problem that could be addressed by a correction in the field. Each was publicized in the enforcement report. It is not clear whether the agency regards the Travenol matter as less or more serious than these recalls, but it clearly treated it differently for reasons that are not as yet clear.

[176] 21 CFR, part 7, subpart B.

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B. TAMPON WARNINGS

During 1980, the Centers for Disease Control and the FDA revealed evidence linking tampon use with toxic shock syndrome [TSS], a recently recognized disease that occurs most often in menstruating women under 30. The disease is serious and can result in death. It is believed to be caused by a bacterium, staphylococcus aureus, and its symptoms include a rapid drop in blood pressure and shock.

Data concerning this disease were first published in May 1980. The Centers for Disease Control [CDC] found that 95 percent of the reported cases occurred in women, and that TSS almost uniformly occurred during the menstrual period. Evidence developed later in the year by the State Health Departments of Utah, Wisconsin, and Minnesota, as well as by CDC, demonstrated a relationship between Toxic Shock Syndrome and the use of tampons during menstruation. While the evidence revealed at least some association between TSS and all the brands of tampons then on the market, Procter & Gamble's RELY brand was most clearly associated with the incidence of TSS.[177] In response to public and governmental pressure, Procter & Gamble entered into a consent agreement with FDA which provided for the recall and removal of RELY from the market. Numerous product liability suits are currently pending against Procter & Gamble alleging defects and negligence in the design, manufacture, and testing of RELY.

On October 21, 1980, FDA published for comment a proposed regulation that would require manufacturers to label tampon packages with a warning that would alert users to the risk of TSS and encourage them to obtain prompt medical attention when the early symptoms of the disease are observed.[178] The agency stated that the public health problem raised by the relationship between tampons and TSS needed to be dealt with rapidly, so it reduced the comment period on its proposal from 60 to 30 days, and it proposed to make the regulation effective quickly, that is, 60 days after final publication.[179]

During this period of extreme interest in 1980, manufacturers of tampons began to take actions voluntarily to protect the public health and their own legal positions. For example, International Playtex began labeling its tampons using the warning language proposed by FDA in October 1980. Johnson & Johnson and Kimberly-Clark also began labeling. Tampax began including a patient package insert addressing the TSS/tampon issue.

Despite FDA's statements in its October 1980 labeling proposal that is was shortening the comment period to 30 days because the association of tampons with TSS is a public health problem that needs to be dealt with promptly, the agency failed to act on the proposal until June 22, 1982—a delay of 1 year and 8 months.[180] During this period, TSS has remained a threat to the lives of many young women. The CDC stated that 867 cases of TSS were reported in 1980 and 492 cases in 1981.[181] The figures for 1981 are particularly disquieting because they occurred during the period of FDA inaction

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[177] 45 F.R. 69840, Oct. 21, 1980.
[178] Id.
[179] Id., proposed section 801.430(e).
[180] 47 F.R. 26982, June 22, 1981.
[181] Hearings, supra, note 3, p. 121.

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on the proposed warning. The CDC also advises that although TSS incidence figures are now remaining constant, they are the product of a surveillance system that does not detect all cases. In fact, CDC has assumed that the reported incidence figures reflect 15 percent of the cases which actually occur. This leads CDC to estimate the true rate of severe cases of TSS to be 300 to 400 per month, and, if milder cases of TSS are as common as severe cases, the actual rate of the disease to be in the vicinity of 600 to 800 cases per month.[182] Based on these and other estimates, FDA took pains in its Federal Register proposal to refute comments that the incidence of TSS is now decreasing and that the incidence of TSS was related solely to the use of one tampon brand, Procter & Gamble's RELY that was removed from the market in 1980.

FDA justified the 20-month delay in finalizing the warning requirement, in part, by citing industry's voluntary efforts to supply information to consumers on TSS.[183] Yet, a review of those voluntary efforts discloses a less than satisfactory performance. Initially, after the revelations of 1980 concerning TSS, many firms (excluding Tampax) began to include permanent warning information on their labels. However, apparently due to the passage of time without final FDA action, the firms, perceiving their interests to be better served through less open communication with consumers, bowed to the forces of the free market and removed the warnings from their labels.[184] Tampax, the industry leader with a reported 58 percent market share of the $410 million tampon market,[185] has never put warnings on its labels, and it has included information on its package inserts describing TSS that has created the impression that the disease posed little risk to women:

> TSS is a very rare illness that affects mainly women during menstrual periods. U.S. Government reports show about 750 cases of TSS among 52,000,000 menstruating women in 1980, with a sharp drop in new cases since September 1980.[186]

In fact, the FDA has agreed with estimates based upon reported studies that the incidence of TSS is between 6 and 17 cases per 100,000 menstruating women.[187] This rate extrapolates to between 3,100 and 8,800 cases among the 52 million menstruating women used in the Tampax insert as a base. Not only is the incidence of risk therefore substantially understated in the insert, but the wording of the notice suggests that the incidence is decreasing. This later statement is also a misrepresentation. In the June 22 Federal Register notice, the agency engaged in a substantial refutation of industry arguments that the incidence of TSS is decreasing. Referring to the CDC estimates and to data developed by State health departments, the agency stated that it was "concerned that many people seem to believe that the incidence of TSS is decreasing." The agency stated that it "disagrees . . . that there is a basis for concluding that the incidence of TSS is now decreasing or that the incidence of TSS is related solely to the use of RELY brand tampons." [188]

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[182] 47 F.R. at 26982.
[183] Hearings, supra, note 3, pp. 109–10.
[184] Id., pp.119–20. The firms moved the information to inserts included within the box.
[185] Chicago Tribune, May 6, 1981, p. 3.
[186] Hearings, supra, note 3, p. 112.
[187] 47 F.R. at 26985. The Centers for Disease Control have developed incidence estimates of 600 to 800 new TSS cases per month that corroborate this projection.
[188] 47 F.R. at 26982.

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In the face of this diminishing, and even deceptive, provision of information to consumers, the agency's decision to permit 6 months of continued marketing by the tampon industry before the final warning regulation published in June 1982 took effect appears to be a needlessly dangerous outcome.

Tampons are a class II device, placed in that category because the agency accepted the opinion of its expert advisory panel that mandatory performance standards are necessary in order for the device to be safe and effective.[189] The agency's failure here—as with every other class II device—to promulgate any performance standard to regulate tampon design or manufacture provides a concrete illustration of the consequences of its approach to class II devices. FDA explicitly recognized the importance of tampon absorbency to the risk of TSS, and it included in the final regulation a requirement to advise consumers to use tampons "with the miminal absorbency needed to control menstrual flow." [190] This requirement arose from the agency recognition that at least one study had found a statistically significant relationship between TSS and tampon absorbency.[191] The importance of absorbency to the risk of TSS was recently confirmed by a joint panel of the National Institute of Medicine and the National Academy of Sciences which issued a report advising women, among other things, to avoid the use of "super plus" or highly absorbent tampons because of their increased risk.[192] Furthermore, FDA reported that there is now no common understanding of the terms ("regular," "super," "super-plus") manufacturers use to describe the absorbency of their products. It concluded, therefore, that "consumers could not identify those lower-risk tampons from product labeling." [193] Thus, a woman seeking to purchase a low absorbency product might buy a "regular" tampon manufactured by one company and end up with a product that is more absorbent—and riskier—than another manufacturer's that is labeled as "super" absorbent.

Even in a circumstance as clear as this, where the agency has recognized the importance of a particular performance attribute to public safety and where current marketing is providing information that will mislead consumers who are seeking to protect themselves, the agency steadfastly has refused to break its perfect record and commence a standard setting proceeding. It prefers, instead, to rely upon the development of a voluntary standard by the tampon industry with no timetable specified for its completion and no guarantee that companies will adhere to it.[194] In the meantime, women are left on their own to experiment with these products in the hope that they will find one that suits their needs before they find one that injures them.

C. RECLASSIFICATION OF CONTACT LENS MATERIAL

Obtaining premarket approval from FDA to market a class III medical device is an expensive and lengthy process, the exigencies of which

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[189] 45 F.R. 12715, 12717 (1980).

[190] 21 CFR, sec. 801.430(d)(3).

[191] 47 F.R. at 26987.

[192] Toxic Shock Syndrome: Assessment of Current Information and Future Research Needs, National Institute of Medicine (released June 4, 1982). Science, Vol. 216. June 18, 1982, p. 1300.

[193] 47 F.R. at 26987.

[194] Hearings, supra, note 3, pp. 121–22.

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make it very difficult for small firms to obtain approval.[195] Where premarket approval is necessary to protect the health and safety of the public, these requirements are unquestionably justified. But where experience demonstrates that rigorous premarket review is no longer necessary, its continuation becomes onerous, and it can cause substantial economic dislocation.

In January and March 1981, the Contact Lens Manufacturers Association petitioned the agency, pursuant to section 513(e), to reclassify the materials from which certain contact lenses are made from class III into class II.[196] The January 1981 petition covered lenses made principally of hydroxyethyl methacrylate [HEMA], and the March 1981 petition covered lenses consisting principally of rigid gas permeable plastic materials. The HEMA petition centered on CLMA's argument that FDA had substantial experience with these devices over their 12 years of marketing and that there is no evidence of any significant health problems relating to their use. The gas permeable materials petition argued that compliance with a revised standard of the American National Standards Institute would provide adequate protection for the public health. The association amended its two petitions in March 1981, and in April the FDA expert advisory panel charged with responsibility for ophthalmic devices reviewed them. The panel was satisfied that the petitions should be approved. It asked for some modifications which CLMA submitted satisfactorily in June 1981.[197]

FDA was silent for 5 months. It then published on November 18, 1981 a statement in the "Federal Register" that the petitions were deficient—that "they are not adequate to satisfy all the requirements" of 21 CFR section 860.123 of the regulations governing reclassification of devices pursuant to section 513(e).[198] Inexplicably, FDA did not specify to CLMA or to other interested parties what the precise problems with the petitions were. The notice opaquely stated that while the petitions could not pass muster, their intent was "meritorious." Rather than return the petitions to CLMA for correction or supplementation, the agency summarily classified the petitions as "moot," apparently because it decided to undertake, on its own, to do whatever work it believed necessary to cure the deficiencies it perceived in the petitions. This failure to accept or reject left the matter in limbo, totally within the discretion of the agency. As Congressman Whittaker aptly noted.

> Mr. WHITTAKER. On what basis was the provider of this information supposed to act if they had given you a battery of material, and you declared it inadequate but did not tell them in which way it was inadequate? Were they supposed to mindread just what the information was you really desired before you would consider it adequate?[199]

As justification for this approach, the acting Bureau Director testified that the agency believed it could conduct a literature review to gather "new information" about the safety and efficacy of these devices—as required by section 513(e)—faster than CLMA could.[200] The

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[195] See the Harris Survey, pp. 61–68, infra.

[196] Section 513(e) provides that, "based on new information respecting a device, the Secretary may upon his own initiative or upon petition of an interested person, by regulation, (1) change such device's classification. . . ."

[197] Hearings, supra, note 3, p. 29.

[198] 46 F.R. 57648, Nov. 24, 1981.

[199] Hearings, supra, note 3, p. 30.

[200] Id.

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agency shouldered this responsibility, apparently, in part to make amends for its slow pace of dealing with the petitions and also because the agency believed that these devices should no longer be subject to the rigors of premarket review. Unfortunately, with a friend like FDA, CLMA needed no enemies. As of the date of hearing on this matter, 8 months after the agency moved ahead on its own, no formal action had been commenced to reclassify these devices.[201]

The agency's decision to freeze CLMA out of the process of gathering evidence to support the reclassification was ill--advised. First, the agency was understaffed. The people who were called upon to repair the deficiencies in the petitions were employed in the ophthalmic devices section, the busiest part of the Bureau of Medical Devices.[202] In fact, the agency had to add staff from another bureau organization who were not experienced in the eye care area to aid in the conduct of the literature search.[203] Second, the agency was hamstrung by section 520(c) of the act which prevents it from using information obtained from other parties in their premarket approval applications to reclassify a device. It thus put the agency on precisely the same footing as any outside party seeking to adduce evidence adequate to justify a reclassification. Third, it is hard to believe that agency employees taken away from their normal duties would be motivated to move rapidly to cure deficiencies in the submission of a trade association presumably capable of representing the best interests of its members and able to gather evidence of the safety and efficacy of the products they manufacture.

What makes the agency's sluggish performance in this matter more troublesome is that there was virtually uniform support for reclassification in the industry and within the agency, as Congressman Whittaker established at the hearings, and there are deleterious effects that the delay has had upon the smaller firms in this industry and upon the public:

> **Mr. WHITTAKER.** Would not the reclassification of the hema and gas-permeable lens materials to a class II device encourage a greater variety of small manufacturers to enter the field, thus potentially reducing the cost to consumers and providing a greater variety of the products?
>
> **Mr. HAYES.** Well, I don't know the industry well enough to be able to give you a definitive answer, but it would certainly seem to make sense from what I do know of it, and from the facts of the case, that if you reclassify—and therefore—improve the ability for more small manufacturers to engage in this in a successfully competitive way, then clearly there would be more competition.
>
> Whether that would lower prices I don't know. I would presume and hope so.[204]

Unfortunately, small firms restricted to marketing their less competitive, less desirable lens materials will not be able to survive FDA's delay much longer. Comments filed in support of the reclassification petition make clear that these firms have been forced to reduce their employment and that they are suffering operating loses while waiting for the reclassification which the entire industry saves for those companies which have previously obtained premarket approvals.[205]

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[201] Section 513(e) prescribes reclassification by a regulatory process that requires the Secretary to publish the recommendation of the expert panel to which a petition was referred and to engage in a notice and comment process prior to promulgatio

[202] Hearings, supra, note 3, p. 30.

[203] Id., p. 34.

[204] Id., pp. 95–96.

[205] Id., pp. 36–94.

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One year after the agency "mooted" CLMA's petitions, and undertook on its own to develop support for reclassification, it published a proposal in the Federal Register to reclassify these materials from class III to class I.[206] CLMA had petitioned to move the devices into class II, but the FDA has tentatively decided "there is no need to establish a performance standard" to provide adequate assurance of safety and efficacy for these contact lens materials. There are three primary reasons articulated for its decision. First, since the mid- to late-1970's, contact lenses made from these materials have been marketed and have been shown to be safe and effective. The absence of reports of significant adverse side effects reported to the Device Experience Network during this period apparently weighed heavily in arriving at this conclusion. Second, the FDA states that the 510(k) premarket notification requirement, and its regulations implementing the requirement, "will enable FDA to insure that only . . : contact lenses that are safe and effective will be marketed."[207] Third, the FDA states that application of the GMP regulations "will enable FDA to insure that only . . . contact lenses of uniform quality will be marketed."[208]

One aspect of the FDA's proposal, in particular, raises questions: The agency may intend to rely too heavily—or improperly—upon the 510(k) process for assurances of safety and efficacy. Although, on its face, the proposal is to move the devices from class III to class I, it seems that the agency may intend in the substantial equivalence review in the 510(k) process to treat the devices as if they were moved to class II and were subject to a performance standard. The FDA's intentions in this regard are suggested by its statements listing the numerous parameters along which substantial equivalence decisions will be made, and by its statements that its substantial equivalence decisions will enable it to assure that the lenses possess the desired properties and characteristics to a clinically significant degree.[209]

These statements signal an intention to use the 510(k) process to achieve adherence to a de facto performance standard. That is, the agency's strict insistence on a high level of similarity between new products and reclassified contact lenses will ultimately become the de facto application of a performance standard where the characteristics of the reclassified materials, to which new products must be substantially equivalent, have become the "standard."

Of course, all substantial equivalence judgments in the section 510(k) process can be said to involve assessing a new device against the "standard" represented by another device to which it is claimed to be substantially equivalent. But distortion of this process occurs if it is taken to an extreme, where equivalence is construed so narrowly that no differences between devices will be tolerated. At that point, the FDA will be using the characteristics of the reclassified devices as a performance standard which all new devices must meet. While this regulatory approach may not directly contravene any explicit provision of the device amendments, it certainly contravenes Congress' intention that when manufacturers of devices are to be required to adhere to a performance standard they be informed in advance of the

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[206] 47 F.R. 53402 (Nov. 26, 1981). 47 F.R. 53411 (Nov. 26, 1982).
[207] 47 F.R. at 53405, 53406, 53414, and 53415.
[208] Id.
[209] Id.

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elements of that standard so that they may structure their engineering and manufacturing processes accordingly. Creating a de facto performance standard through the 510(k) process leaves manufacturers in the dark over the manufacturing criteria they will be held to, and vests the FDA with a level of discretion that Congress did not intend.[210] If the agency believes that adherence to a performance standard is necessary to assure that contact lenses are safe and effective, it should reclassify them into class II and commence the necessary standard setting proceeding.

D. BIFOCAL SOFT CONTACT LENSES

In the early 1970's, firms began to obtain FDA approval to market soft contact lenses. Later in the decade, research and development led to the emergence of a bifocal soft lens, a portion of which is of a different power, in order to provide both distance and near vision correction. FDA monitored the development of the bifocal soft lens, and on several occasions it made the industry aware that no bifocal soft lens could be marketed without prior approval by FDA. As early as June 1980, the agency issued guidelines stating that if a manufacturer changes either the configuration or the indications for use of a previously approved soft contact lens, it is required to conduct clinical testing on the lens to establish its safety and efficacy and to submit a PMA and obtain prior FDA approval to market the modified lens.[211] In July 1981, during on open meeting of the Ophthalmic Device Section Advisory Committee, the committee members (all highly qualified experts in this field) repeated the need for clinical testing and FDA approval prior to the marketing of a bifocal soft lens.[212]

In August 1981, Bausch and Lomb notified the agency that it was adding a bifocal soft lens to its line of previously approved soft contact lenses. FDA also learned in September that the Wesley-Jessen division of Schering Plough was marketing bifocal lenses. Both companies were on notice that FDA required a submission of clinical evidence prior to marketing, yet neither company undertook to supply data establishing the safety or efficacy of these new devices.[213] Over the next 3 months, the agency and the companies pressed their respective views regarding the need for premarect approval in correspondence and meetings. Yet, while the parties were posturing, the companies were commercially distributing the lenses.

There was never any room for question about FDA's position in regard to the legality of these firms' behavior either prior to or after it learned they had commenced marketing these bifocal soft contacts. On October 7 the agency reiterated its consistent position in a letter to Bausch and Lomb and Wesley-Jessen and to all other manufacturers of soft contact lenses stating:

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[210] See discussion of the 510(k) process at pp. 32–35, supra. The Subcommittee recognizes that Congress did invest the agency with a measure of discretion by providing for a flexible interpretation of the term "substantial equivalence". It is also recognized that the legislative history reflects Congressional intention for the term to be construed narrowly where differences between "new" and marketed devices have a bearing on safety and effectiveness. House Report, supra, note 6, pp. 36–37.

[211] Hearings, supra, note 3, p. 115.

[212] Id.

[213] See, e.g., Letter from Michael Fitzpatrick, Regulatory Affairs Administrator, Bausch and Lomb to Jean McDowell, Chief, Document Control Center, FDA, Aug. 21, 1981, printed at id., p. 110.

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> Modification of such lenses in design and indications for use constitute substantial changes which require FDA approval prior to marketing. Until such approval, these lenses may only be distributed as investigational devices for investigational use."[214]

Nevertheless, the agency—despite its numerous, unequivocal statements regarding the illegality of commercial distribution—waited until December 29 before asking the appropriate U.S. attorneys to commence seizure actions against Bausch and Lomb and Wesley-Jessen. During the 3½ months while the companies were sparring with FDA, they were gaining substantial economic benefits from being the first on the market with this new product.[215] The reason they were first was not necessarily because their devices were developed first; it was because competing firms (like Ciba-Geigy and Salvatori Ophthalmics) respected FDA's statements regarding the need for prior approval and clinical data.[216] These and other firms' reward for complying with FDA's expression of the requirements of the law was to lose significant competitive advantage to firms that defied FDA.

In addressing the length of time it took the agency to move formally against the offending firms, FDA's chief counsel testified that "three and a half months from identification of a problem to transmitting an enforcement action to the U.S. attorney's office is pretty prompt for the FDA in this area." [217] Yet, as Mr. Scarlett agreed, a seizure pursuant to 21 U.S.C. section 334 of these companies' devices would have been neither a complex nor a difficult proceeding to undertake from the Government's standpoint. In fact, preparing a seizure case is one of the simplest actions that a lawyer in food and drug practice can prepare, and it did not take 3 months to prepare these cases.[218] The reason for the delay appears to have been the time necessary for the agency internally to debate its substantive position in the matter even though it had informed the companies directly in regulatory letters that it was unlawful to market the lenses without submitting data,[219] and even though it had previously made the clear, industry-wide announcements of its position in June 1980 and in July 1980.

> Chairman DINGELL. Didn't you tell Bausch & Lomb this was a violation of law?
>
> Mr. SCARLETT. Yes, we did.
>
> Chairman DINGELL. And you told them well before the three months, did you not?
>
> Mr. SCARLETT. Yes, we did. But when we go into court we want to be certain what we are saying is correct.[220]

What is disturbing about this colloquy is not the agency's desire to be certain before commencing judicial proceedings, but the implicit statement that the agency actually considered *not* commencing an action because its position might not have been "correct." This point was made explicit in Mr. Scarlett's February 15, 1983 letter to the subcommittee staff where he states that the November 23, 1981 meeting "was no pro forma meeting serving only as a checkpoint before an inevitable decision to refer the cases . . . the important point is that

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[214] Letter from Ann Holt, Associate Director for Compliance, Bureau of Medical Devices, to various contact lens manufacturers, Oct. 7, 1981, printed at id., pp. 108–109.

[215] Id., p. 112.

[216] Id., p. 115.

[217] Id., p. 114.

[218] Id., pp. 112–13. In a subsequent letter to subcommittee staff, Mr. Scarlett stated that the decision to go forward with the cases was no made until Nov. 23—5 weeks prior to his transmission of the matter to the U.S. attorneys.

[219] Id., pp. 107, 114–15.

[220] Id., pp. 113–14.

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even as late as November 23, the agency had not decided that the companies' legal position could be defeated in court."

When the agency intends for an entire industry to be governed by a statement of policy, it seems essential that those within the agency who will bear responsibility for enforcing that policy be involved in its formulation and satisfied with that policy. Otherwise the agency runs the risk of failing to back itself up by taking prompt, appropriate enforcement action against firms that disregard that policy in an effort to gain economic advantage. Such failures will compromise the agency's credibility and makes it far less able to secure voluntary compliance with agency pronouncements in the future.

Also troublesome is the fact that the offending parties here were large firms in an industry where small firms proliferate. The leisurely pace of law enforcement actions against Bausch and Lomb and Wesley-Jessen had the effect of benefiting those who needed it least and prejudicing those who would suffer the most.

The seizure complaint against Wesley-Jessen—alleging that the lenses were adulterated because they were not covered by an approved PMA—was filed by the U.S. Attorney with the U.S. District Court for the Northern District of Illinois on January 4, 1982.[221] On February 2, 1982, the U.S. Marshal seized lenses within the judicial district, but Wesley-Jessen continued to market the bifocal soft contacts elsewhere. On February 16, the agency sought and was granted a temporary restraining order against further marketing of the devices by the company, and on March 18, the agency obtained a preliminary injunction.[222]

The seizure complaint against Bausch and Lomb, finally forwarded for filing to the U.S. Attorney in Buffalo, N.Y. on December 29, was never filed. Instead, the parties negotiated a consent agreement that was finalized on January 22, 1982. As part of the negotiations, Bausch and Lomb agreed, on January 12, to cease further commerical distribution of the lenses. The consent agreement prohibited further sale or promotion of the device by Bausch and Lomb until FDA approved it. It also required the company to notify its customers, primarily wholesalers and distributors, of FDA's position regarding the lenses, and to ask its customers to certify that they will not sell their lenses already in their inventory.

The agreement also reflected the fact that Bausch and Lomb—at the same time it was unlawfully marketing its lenses—was conducting a clinical trial to determine whether the devices were safe and effective. Hedging its bet in this manner, the company had engaged in a parallel marketing scheme whereby it gathered evidence of safety and efficacy while commerically distributing its product. Then, if the agency prevailed, the company apparently expected to reconstitute the data as an application for premarket approval. The consent agreement contained FDA's agreement to accept this post-marketing data as a supplemental PMA application, to review it to determine its sufficiency, to forward it to the appropriate panel for review, and to issue an order approving or denying the supplemental application.[223] This agreement to evaluate

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[221] *U.S. v. Article of Device* . . . "One Sterile Lens Durasoft 2 . . . ," No. 82C0013 (N.D. Ill., filed Jan. 4, 1982).

[222] *U.S. v. Wesley-Jessen, Inc.*, No. 82C874 (N.D. Ill., injunction issued Mar. 18, 1982).

[223] Consent Agreement, p. 6, annexed hereto at p. 71 et seq.

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Bausch and Lomb's clinical data raises further questions about FDA's handling of this matter.[224]

Foremost among these questions is the fact that the research appeared to violate FDA's regulations governing these investigations. The statement of informed consent provided to subjects in the study stated that the bifocal soft contact lenses were "already approved by FDA and already on the market" and that the study was being conducted "to confirm" their efficacy.[225] These assertions to subjects appear to violate regulations which forbid a sponsor from representing that an investigational device "is safe or effective for the purposes for which it is being investigated" (21 CFR section 812.7(d)).

It is also arguable that use of the informed consent form containing the false characterizations violated FDA's general informed consent regulations which require consent to be sought "only under circumstances that provide the prospective subject . . . sufficient opportunity to consider whether or not to participate . . ." (21 CFR sec. 50.25). It appears reasonable that prospective study subjects might have altered their decision whether to participate in the study based on the knowledge that the bifocal lens they would be wearing had not been approved by FDA and that the study was to determine whether the device was safe and effective. Finally, the assertion that the bifocal soft lenses were already "approved by FDA" appears to contravene section 301(1) of the act, which prohibits:

> The using, on the labeling of any drug or device, or in any advertising relating to such drug or device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect under section 505, 515 or 520(g), as the case may be, or that such drug or device complies with the provisions of such section.

The act defines "labeling" to mean "all labels and other written, printed, or graphic matter (1) upon any article . . . or (2) accompanying such article". (21 U.S.C. sec. 201(m)). The statement of informed consent certainly accompanied the devices and provided information about their properties, safety, and efficacy. If this information is considered labeling, then it is in violation of law because it clearly stated that the lenses were "approved by FDA" when, in fact, they were not.

The agency was aware of these deficiencies in the conduct of Bausch and Lomb's research.[226] It was faced with a choice. On the one hand, it could permit Bausch and Lomb to rely upon research premised upon "FDA-approved" status of the devices being investigated, which was conducted after the product was in commercial distribution, and in which subjects were told (and presumably influenced by the fact) that the devices were "approved." On the other hand, the agency could insist the research meet the generally applicable standards for investigational devices under which every other manufacturer was attempting to get bifocal lenses onto the market. The agency, of course, had consistently maintained since the beginning of its direct

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[224] Staff was advised in a July 8, 1982 telephone interview with Dr. George Murray of the FDA that the agency had tentatively found Bausch and Lomb's data to be acceptable, that it had been referred to the expert panel for study, that the panel had reviewed the data and had recommended acceptance of the application and that the agency was preparing to approve the application within the next 4 to 6 weeks. Utlimately, the application was approved on Nov. 16, 1982.

[225] Hearings, supra, note 3, p. 132.

[226] Id., pp. 131–35.

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dealings with Bausch and Lomb and, indeed, since 1980, that bifocal soft contact lenses were investigational devices.

The agency adopted the former course. Pursuant to the consent agreement, it tentatively evaluated the research, forwarded it to the appropriate advisory panel for review, and in turn, received the panel's recommendation to approve the lenses, and took final action approving them in November 1982.[227] Both Commissioner Hayes and Chief Counsel Scarlett testified that the agency concluded it would not be "in the public interest" to force this company to perform duplicate tests that met the requirements of its investigational research regulations.[228] Such a course would have "penalized" the company, while all the agency sought to do was to get the offending device off the market.[229]

From the perspective of Bausch and Lomb's honest competitors, who chose to abide by FDA's dictates on the requirements of the law, the agency's decision adds insult to injury. Not only were they prejudiced by Bausch & Lomb's early, unlawful entry into the market, but they saw the company permitted to rely upon research data gathered after the unlawful marketing commenced which failed to comply with FDA regulations. The agency's failure to follow through with internal policy decisions that support its public policy pronouncements has taught the regulated industry a lesson: voluntary compliance with agency policy is fraught with the risk that those who fail to comply will gain an advantage.

It could be argued, in justifying the agency's disposition of this matter, that its statutory mandate relates solely to protecting the health and safety of the public and that this does not always mesh with protecting the competitive health of industry. But to protect public health, the agency must be able to secure the cooperation of industry without the need, on all occasions, to resort to judicial proceedings. Industry's willingness to cooperate is tied, understandably, to companies' assessments of the consequences of a failure to comply voluntarily with agency statements of policy. When, as here, companies see a failure to cooperate that results, at worst, in leaving the offender in status quo ante with no "penalty" imposed, and, in actuality, with a "leg up" on competitors, the incentive for future cooperation is jeopardized.

The subcommittee finds that if the FDA is to be able effectively to call upon manufacturers to take action voluntarily to comply with its pronouncements on the requirements of the law, then it must be prepared to act promptly and convincingly against companies who see their economic self interest to lie in pursuing contrary individual courses of action. To do less compromises the agency's credibility and its ability to deter unlawful conduct that potentially threatens the public health and safety.

VIII. THE ROLE OF COST BENEFIT ANALYSIS IN MEDICAL DEVICE REGULATION

Since 1981, there has been a recurrent regulatory approach contributing to FDA's failures to adopt an adverse experience reporting

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[227] See n. 224, supra.
[228] Hearings, supra, note 3, p. 132.
[229] Id.

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system, to adopt a regulation restricting the sale or conditions of use of devices, and to begin setting performance standards for class II devices. Contributing to each has been the nonstatutory change in decisionmaking standards made by the current administration as evidenced by Executive Order 12291, issued by President Reagan on February 17, 1981. Whether it was cited explicitly or relied upon implicitly (as in the search for the "most cost-effective" alternative) the Executive order, or the increased emphasis placed upon cost/benefit in decisionmaking, clearly was a factor in each of these decisions to delay, defer, or default from FDA's statutorily-mandated responsibilities.

Commissioner Hayes was questioned at length by Chairman Dingell and Congressman Gore on the reasons the agency held in abeyance its proposed regulation requiring adverse experience reporting. The Commissioner testified that his "chief reason" was that he is "really not certain about the best way to do it." [230] He acknowledged at the same time that the agency was able to decide on a reporting requirement for all unique, new high technology devices approved since 1976 but claimed the agency was unable to resolve how to gather such information for the remaining products on the market.[231] This makes the "chief" explanation hard to swallow. Six years of experience in gathering reports from many manufacturers, together with the information gathered in the nowsuspended rulemaking proceeding, is a more than sufficient basis to draft a regulation governing the remainder of devices on the market.

In fact, this extensive experience has not been sufficient. The Federal Register notice announcing suspension stated that "FDA has become subject to requirements more extensive than those in effect at the time of publication." [232] Those requirements included not only Executive Order 12291, in light of which the proposed rule had to be reviewed, but also the inevitability that any proposed rulemaking would be subject to the scrutiny of ranking executive branch officials within the Department of Health and Human Services and the Office of Management and Budget. Commissioner Hayes' testimony confirms that, whether or not he suspended the rule in deference to OMB's specific direction, he was keenly aware of, and his reasons were premised on, the philosophy central to the Executive order:

> There is no question that one of the reasons that I and I alone made the decision that this rule should be put in abeyance was because I felt cost-benefits, appropriateness, and efficiency of reporting were important. Cost effectiveness and the like are terribly important.[233]

When Chairman Dingell inquired into the legal basis supporting the suspension decision, the following colloquy ensued:

> Chairman DINGELL. Where, Mr. Scarlett or Dr. Hayes, in the basic statute under which you labor on this particular point is there a statutory exemption to allow you to respond to the administration's demand that the regulations be cost-effective? Where is there the authority for the OMB to tell you to withhold action, particular action, with regard to medical devices experience reporting?
>
> Chief Counsel SCARLETT. [after quoting the language of Section 519 which authorizes reporting regulations] I don't think you could point to any specific legal requirement for which OMB is responsible.

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[230] Id., p. 11.

[231] The agency uniformly conditions approval of all new class III devices to require manufacturers to report adverse experience and other essential information. Id., pp. 27–28.

[232] 46 F.R. 57568 (Nov. 24, 1981).

[233] Hearings, supra, note 3, pp. 22–23.

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> Chairman DINGELL. First of all [section 519] doesn't give OMB the power to tell you about regulation, does it?
>
> Mr. SCARLETT. That is correct. This is my understanding.
>
> Chairman DINGELL. The second point is that nowhere in that language does it require that the regulation be found to be cost effective, does it, or that it be precleared with OMB?
>
> Mr. SCARLETT. It doesn't use the words cost effective.
>
> Chairman DINGELL. It does not. Now, I have asked you to tell me specifically where in the statute as regards to cost-effectiveness, or as regards to the OMB's oversight is authorized.
>
> Mr. SCARLETT. There is nothing in the Act specifically authorizing that.[234]

Reliance upon the vagaries of cost-effectiveness also contributed to the agency's decision to withdraw the proposed regulation restricting various categories of devices and behind its program to rely on alternatives to performance standards for class II devices. The restricted device proposal, developed by the Carter administration 4½ years after enactment of the device amendments, was withdrawn on the same day that the mandatory experience reporting proposal was suspended. Again, the Federal Register notice referred explicitly to the more extensive requirements imposed by the Executive order.[235] The agency noted, however, that it retained authority under the existing prescription devices regulation (21 CFR section 801.109) to restrict the sale and distribution of certain devices (see discussion at pp. 30–31 supra). The draft policy statement on class II devices opened with the statement: "The FDA will use the most cost-effective regulatory alternative to address class II medical device problems." [236] This left the congressionally mandated system of mandatory performance standards relegated to the status of a last resort, to be resorted to only when all other voluntary means failed.

The increased emphasis on cost effectiveness in these instances appears to have created an impediment to effective public protection. Three of the major provisions in the device amendments now lie in limbo as result of the application of cost benefit analyses. The following colloquy between Chairman Dingell, Commissioner Hayes, and Congressman Gore eloquently conveys the subcommittee's reason for concern:

> Chairman DINGELL. Doctor, I think it is becoming quite plain to you from our discussion today, mine, Mr. Gore's comments, Mr. Whittaker's comments, that this subcommittee is very, very much troubled with the idea that we passed statutes which impose clear duties, responsibilities, guidelines for behavior on agencies. We are troubled that those guidelines are not carried out, and that the agency does not do that which the law mandates the agency to do. We are also troubled, perhaps more so, that OMB comes forward and says that you are supposed to act—you and the other regulators inside of Government—are supposed to act on the basis of a cost-benefit ratio. We find no evidence of a congressional intent to that effect, yet we read here in your pronouncements, as referred to by Mr. Gore and by the Chair, that you have acted in certain matters with regard to a finding of cost-benefit. You say, of course, this is your judgment, and that you were not responding to OMB's instructions; yet you cite OMB's instructions, and you use almost in haec verba the language of OMB.
>
> * * * * * * *
>
> Commissioner HAYES. I do think, as just a matter of principle, that some of the things embodied in that executive order—that is, that before one writes a regulation or mandates anything, or, in fact, takes any action—that one asks: is it needed, what is it going to cost, not just in dollars, but the total costs, what

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[234] Id., p. 28.

[235] 46 F.R. 57569 (Nov. 24, 1981).

[236] CCH Medical Device Reports, par. 17,582, p. 17,804. Jan. 26, 1982.

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are you going to get for what you do? To me, it is irrational to write Government regulations or impossible rules and regulations on a medical center or anywhere else unless there is a reason for doing it, and you know how much it is going to cost you immediately or in the future, and you know your ability to implement the rule. These are questions that I would ask of anything that we do at the Food and Drug Administration as long as I am Commissioner, with or without any such executive order.

Congressman **Gore.** But it says more than that. It says undertake regulatory actions only when the benefits outweigh the costs. If that is the standard, if there is a requirement not to act until the calculated benefits outweigh the calculated costs, that is a burden that prevents—that will often prevent the public from receiving the protection that it needs. There are specific devices that are held up and now regulated just like tongue depressors. They include—let me read you this list-cardiac monitors, neonatal incubators, ventilators, respirators, anesthesia machines, implanted spinal cord stimulators for pain relief. These are all devices that, because of a holdup, are being looked upon in the same manner as tongue depressors. The public, I think, is entitled to the kind of protection that this law gave them. It is a perfectly reasonable law.

* * * * * * *

Chairman **Dingell.** Doctor, I just want to observe that much of what is in the executive order I regard as good sense. It would probably be done by a good regulator, but I don't regard the good sense mandates of that as being a substitution for the clear intention of the Congress unless in some way the OMB has risen, through some bootstrap operation of its own, to a level which is above the law.[237]

The subcommittee's experience with FDA's implementation of the medical device amendments presents important public policy questions regarding the risks of cost benefit analysis when applied to rules promulgated with intent to protect public health and safety. These cases are neither isolated nor unique. Executive Order 12291 is the cornerstone of the current administration's regulatory relief program. Many of its principles were embodied in regulatory reform legislation considered by the 97th Congress and not enacted. While the subcommittee may concede that the regulatory relief efforts during the past 2 years may have resulted in fewer regulations being promulgated, we are concerned by the potential for adverse consequences of those efforts. The examples of the medical device experience reporting regulations and the restricted device regulations provide clear evidence that, in the name of cost effectiveness, the protection of the health and safety of the American people may be compromised or even sacrificed.

Further, the example of the reclassification of contact lens materials presents striking evidence of the real problem associated with the current regulatory process: The problem of delay and its consequences on the ability of business to compete fairly and successfully. The subcommittee observes that nothing in the administration's current "regulatory relief" activities, nor in proposed regulatory reform legislation, addresses the major problem of delay in the regulatory process.

IX. A Survey of the Medical Device Industry's Perception of the Device Amendments and FDA Regulations

In 1980, the Bureau of Medical Devices' Office of Small Manufacturers Assistance commissioned a survey of device manufacturers to assess the impact of FDA regulations on the medical device industry and the reactions of manufacturers to the regulations.[238] The survey

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[237] Hearings, supra, note 3, pp. 129–131.

[238] A Survey of Medical Device Manufacturers. Louis Harris and Associates, July 1982. Study No. 802005. NTIS No. —. Hereafter referred to as the "Survey."

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APPENDIX E

ORTHOKINESIS, INC.

Case Updates for COMCORE B

COMCORE

Fall 1994

Business Finance Assignment

Compare the ratios discussed in your finance book to those presented for the orthopedic industry in the case handout. Some of the ratios in the case are not discussed in the book.

Define the ratios that are not in the finance book. You will have to do a little research to find out their definitions. Some of the suggested sources are Standard and Poor's and Moody's financial reports.

Compute all ratios for OrthoKinesis Inc.

Due date: September 20, 1994.

CASE UPDATES (for Lewis)

1 - New Facility Layout
Reflects current dimensions
and 2 CNC machines

2 - Production Process Times
Note: Share vertical and
Share horizontal
Total: 25 hours

3 - Total Space Currently Used =
100 x 50 + 25 x 25 + 25 + 25 x 100
5000 + 625 + 2500
8125 sq. ft.
20000 - 8125 = 11875 available

Current Production Plan
Elbows

10,000/yr or 833/month
Approximately
200/week

Expect demand to
Increase 10% to 11,000
Next year

Forecast is for a linear trend - no cycles.

Thus, will increase production as per attached schedule:

$Y(X) = 830 + 14(X)$

$Y(1) = 844$
$Y(2) = 858$

$Y(12) = 998$

Total for year = 11,052
Where Y is in month's

1 - Check Capacity's Available
i.e. is it possible to meet demand.

Look at Current Scenario
of 830/ month
or 200/week

Will Look as All
Production Steps

CURRENT CAPACITY INFORMATION
JOINT REPLACEMENT

1 - Mold: 1/hr
Runs 3 shifts / 7 days week
Requires 1 operator

Capacity
24 hrs/day x 7 days/week
= 168/week

Buy Additional Modler

2 - Die: 2/hr
Can redesign dipper
to produce 8 at once

New Capacity: 16/hr

FORGE

4/hour =
32 / 8 hour day
32 x 5 = 160 per week, 1 shift

Need 2nd shift or some OT

Plenty of Capacity

GLAZE

1/hr

Can redesign glazer to 00
16 at once

16/hour current capacity

Plenty of capacity with change

POLISH / BUFF / FINAL BUFF

6 machines available; interchangeable attachments

Each operation takes 1 / hr

Operator is skilled;
Operation follows 90% learning curve

Thus, since each operation
takes 1 hour + haave 2 machines
available to 00 each task,

Can 00 2 / hour for each task

Thus 2 x 8 x 5 = 80 per 5 day
week - 1 shift

Or capacity is 240 / 5 day week
working 3 shifts

Near Capacity

JOINT CUP

Cut / shape/ drill all done on CNC machine

Total time is .75 hr / piece
or 1.33 pieces / hour
or 1.33 x 8 x 5 = 50 pieces per 40 hour week

Thus, 50 x 3 = 150 working 3 shifts

Thus, need weekends;
can barely make 200 pieces / week

CNC machine as capacity
(for joint cup)

JOINT STEM

Cut / share vertical / share horizontal /
drill / tap

Total time = 1.25 hr/piece

Process improvements allow for reduction of cut, shaping operations, and drill by 50%

New total time = .75 hr/piece

Thus, as per joint cup,
CNC machine at capacity

SUMMARY - Key Decisions

1 - Molding machine over capacity

Buy new molder or subcontract?

2 - Polish / buff / final buff
nearest capacity

New machines or
replace with robot?

3 - CNC machines near capacity

Invest in CNC machines
(current type) or
newer technology?

INSPECTION OPERATIONS

Capacity can be increased by adding people since this is completely done by hand (no machine capacity necessary)

ADDITONAL INFORMATION

Space for cnc machine
25' * 25'

Space for new cnc machine
50' * 25'

Space for robut
25' * 25'

New robut capabilities:

All operations: 20* faster

New cnc machine

All operations: 4* faster

OTHER ASSUMPTIONS

1- All machines must be manned at all times (except cnc)

2- 1 operator can monitor 2 cnc machines

3- No additonal space needed for shipping + receiving, tool storage, etc in current facility.

4- Additional space can be leased for 20% premium
Additional space available: 2nd floor, 20,000 sq. ft.

5- No

What will needs be with new line coming on?

CURRENT LEAD TIME: 8 weeks

- need to reduce

- purchase order to

  manufacturing floor = 3 weeks

- material from supplier : 1 week

- manufacturing lead time: 3 weeks

(including subcontractor

time of 1 week)

- packaging + shipment: 1 week

Total 8 weeks

file:sprupdat

Spring 1995

(The team leader is speaking) "We need to improve our design, manufacturing, and business processes." (Someone interrupts.) "What is a process?" "You remember, processes are the mechanisms or work which make things happen. There is a hierarchy of work performed. Individual things we do are called tasks; a collection of tasks are called activities and multiple activities with a common purpose become a process. This hierarchy exists for manufacturing and administrative processes. For example, in the purchasing department they have a process for purchasing materials. The process is a series of activities such as processing purchase orders, securing vendors, placing orders, etc. The activity of securing vendors is made of individual tasks such as soliciting bids, qualifying new vendors, visitations to insure quality, etc." "Oh yeah, I remember now."

" We also need to construct a framework of our processes to develop our value chain. Remember the value chain is made up of building blocks (processes) used to create value for our customers. If we establish cost, cycle time and quality as performance measures then, as a group, we can work on the tasks to improve the activities which will improve the processes. This is the way we can seek continuous improvement. It has a ripple down effect and improves the overall company performance. Our customers should be happier and that will please xxx "

The value chain is the groundwork for an important competitive tool: our relative cost position. To compete successfully, a company must analyze its cost position relative to its competitors. But before the company's relative cost position can be determined, the enterprise must completely understand the behavior of their own costs.

Relative costs are an important part of the competitive situation in an industry because price is a competitive weapon. Strategic cost factors are those cost components that determine a company's relative long-run position. Today's costs related to components such as product design, product costs, productivity, manufcturing overhead, marketing, and other administrative expenses are likely to be the costs we have to live with in good and bad times.

You have to know which costs are relevant in a strategic sense. That is, which costs can influence or be influenced by a new strategy. Strategic cost analysis has the goal of positioning the firm with a sustainable cost advantage by "doing the right thing" in the areas such as cycle time, waste, quality, delivery, unit cost, etc.

> "While accounting systems do contain useful data for cost analysis, they often get in the way of strategic cost analysis" **Competitive Advantage**, M. Porter, 1985, p.63
>
> "One of the most wrenching changes CEOs face is to realize that goals that formulate from (traditional) accounting information no longer permit them to manage companies effectively." **Relevance Regained**," H. Thomas Johnson, 1992, p.3
>
> "While cost accounting takes a historical perspective and focuses on report costs, cost management takes a proactive role in planning, managing and reducing costs." Berliner and Brimson, **Cost Management for Today's Advanced Manufacturing**, 1988, p.3.

The basis for these comments is that "traditional" cost accounting system yield highly inaccurate or distorted data. Traditional cost systems have as a basis, generally accepted accounting principles. GAAP is only concerned with valuation of inventory in aggregate. GAAP represents a fiduciary responsibility for reporting requirements. Therefore, such information should not be used as a basis for product development, positioning within an industry, pricing, etc.

I know that activity-based costing improves product costing and that activity-based management focuses on improving processes. All this sounds well and good but, I am not sure we have the staff and the technical expertise to implement a new cost system.

Total product costs are all items directly and indirectly related to the product. In the past, directly related items were only direct materials and direct labor. We generally call indirectly related costs "overhead" or "burden". I gather from what I have read that the problem lies with the traditional OH and the subsequent allocation of OH using arbitrary bases. I wonder if this new approach is all it is touted to be. We certainly need a decision making system that would answer some strategic questions and promote continuos improvement..

Are we selling the right or wrong products
How about the customers we serve? Are they profitable relationships?
Our new products? Are they priced right? Are they too costly to produce?
Why are we experiencing increases in the cost of production?
Are we outsourcing the right or wrong items (parts or services)?

By the way, have any of you read about the studies that the Arthritis Foundation are conducting on something called "transforming growth factor beta?" That is the scientific name for a substance that has actually repaired arthritis-damaged cartilages in laboratory animals. We better find out all we can about the time table on this research. It sounds like something that could greatly erode our potential market.

The attached articles are intended to supplement and re-enforce the CMS text.

COMCORE B--Spring 1995 Prof. Chris Tilly

ORTHOKINESIS CASE
CASE UPDATE 1: "THE F.D.A. PROBLEM"

To read for January 24, 1995

> As you read this case update, you may wish to refer back to the original OrthoKinesis case to refresh your memory about company personnel, the FDA regulatory process, or other subjects raised in the update. The update is followed by a list of questions. Think about these questions, and try to come up with answers. On January 24 in class, you will discuss the questions with your team to compare notes and try to come up with a set of answers. Then we will discuss the results as a class.

When Charles Waters took the reins of OrthoKinesis in 1992, he quickly discovered that he had inherited a potential time bomb from the previous CEO, "Colonel" Earl Blaylock. Waters started his tenure with a series of in-depth one-on-one meetings with key management personnel. Part-way into Waters's meeting with VP of Manufacturing Ricardo Santiago, Santiago looked Waters in the eye and said, "I don't suppose the Colonel told you about the FDA problem with the Flexi II."

Though Waters was startled, he didn't let on that he had no idea what Santiago was talking about. Instead, he replied, "Well, I've heard the Colonel's version, but I'd lke to hear yours."

The story that Santiago told was a disturbing one. Between 1987 and 1992, OrthoKinesis had introduced three successive elbow models, the Flexi I, II, and III. The original Flexi I elbow featured a titanium joint stem. But in 1988, when work began on the Flexi II, Vice President for R&D Phil Lomax decided to experiment with a plastic (polyethylene) joint stem instead. Using polyethylene reduces materials costs for that piece by $160, reducing total elbow joint costs by about 18%. With approximately 10,000 units per year sold, the potential savings for OrthoKinesis were $1.6 million per year (plus some additional savings from reduced machine wear)--quite substantial for a company whose net income was typically in the range of plus or minus $1 million. Alternatively, the lower production cost could allow OrthoKinesis to reduce the price (or keep price increases low compared to its competitors), potentially expanding its already commanding market share in elbows.

The question was: if OrthoKinesis switched to a plastic stem, would they be able to maintain quality? Plastic is less durable than titanium, and the danger was that the plastic would deteriorate. Mild deterioration could result in polyethylene particles "floating" around the bone and joint, increasing the risk of infection. Severe deterioration would cause failure of the artificial joint, necessitating replacement.

Lomax was confident that his R&D team could redesign the joint to reduce stress on the stem, minimizing deterioration, and eventually he and the Colonel approved a design for Flexi II with a plastic stem. They were able to quickly receive approval from the U.S. Food and Drug Administration (FDA) by arguing that the Flexi II was "substantially equivalent" to the Flexi I.

Although some FDA scientists protested that the change in stem material was a major difference, FDA Director John Villforth was promoting a pro-business appraoch to regulation, designed to help businesses get their products on the market quickly. Furthermore, the FDA's Center for Devices was overwhelmed with device applications, and agency administrators chose to focus their energy on devices that appeared dramatically different or particularly risky.

Within less than a year of the 1989 introduction of the Flexi II, there were already indications that OrthoKinesis had made a mistake. Surgeon complaints of infections in patients who had received the Flexi II substantially exceeded such complaints for the Flexi I (though they still affected only a small minority of patients). Since physicians typically treat infections with antibiotics, not surgery, there was no immediate evidence that the infections were caused by deterioration of the plastic. Even so, the infections worried Lomax and Blaylock enough that they decided to convert back to titanium joint stems for the Flexi III, and to speed up the Flexi III development timetable.

However, Blaylock and Lomax chose not to stop production, recall Flexi II's already in distribution, or issue a warning to surgeons who were past or present users of Flexi II's. They also chose not to report the problems to the FDA. For a medical device such as an artificial elbow, manufacturers are required to report any problems of safety or effectiveness to the FDA. But Blaylock and Lomax reasoned that since they did not have strong evidence for safety problems, they were not required to report. A critical concern, of course, was that a highly publicized FDA investigation, or--worse--an FDA order to cease production or recall the Flexi II's--could kill the company, which had staked everything on its move into production.

When Santiago heard about the problems some time later, he argued strenuously for reporting them to the FDA. But Blaylock overruled him, and also requested that Santiago not discuss the problems with other managers, such as VP for International Marketing Alice Reardon, who was not informed until the following year. Santiago reluctantly complied.

As time went on, evidence mounted that the plastic joint stems were wearing out faster than they should have. By 1991, some surgeons had even begun replacing the elbow joints, and a few notified the FDA directly as well as informing OrthoKinesis. The FDA quietly initiated an investigation. However, Blaylock still held off on notifying surgeons about any potential problems.

That was the situation Santiago described to Waters in 1992. Waters acted quickly. He gathered hs management team for consultation, discovering that 8,000 units of the Flexi II had been sold. Once he had the facts, he informed the Board of Directors. He had already been thinking of replacing Lomax with a new VP of R&D, and this clinched it: he asked for Lomax's resignation and brought in Rocco Gargiulo, an experienced biomedical engineer and manager and an old acquaintance. He pledged full cooperation with the FDA.

However, Waters decided not to go public with the problems, fearing that this would jeopardize the company's survival. He requested that the FDA refrain from publicizing the Flexi II's problems until the preliminary investigation was complete. Waters also did not send out a

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warning to surgeons, nor initiate a recall. As he saw it, he had no choice. Santiago urged Waters to create a separate VP for regulatory affairs, reporting directly to the CEO, rather than leaving regulatory compliance in the hands of the VP for R&D. However, Waters decided against this.

At the end of 1994, the time bomb exploded. Waters and his management team had not been able to defuse it, but through their actions had lessened its impact. FDA spokesperson Hazel Ryan announced publicly that a preliminary investigation of the Flexi II elbows had shown unacceptably high rates of deterioration in some patients, resulting in infections and joint failures. Fortunately, no deaths had resulted. Furthermore, OrthoKinesis had failed to notify the FDA of these problems as they emerged. The FDA was launching prosecution against OrthoKinesis. A court hearing would hear claims from patients and insurers who had suffered pain or financial losses, and would result in a determination of culpability and a setting of penalties, if any.

Both OrthoKinesis and the FDA knew that a trial was likely to reaffirm the FDA's findings. The only real question was the nature of the penalties. In all likelihood, there would be fines amounting to hundreds of thousands, perhaps even millions of dollars.

Upon the FDA's announcement, attorneys specializing in product litigation began searching for patients who had received the Flexi II, in order to enter claims against OrthoKinesis. Insurers also began to comb through their records. Surgeons called with anxious questions about the Flexi II, and the newer Flexi III and IV. Publicly, the Mayo Clinic stated that, "We stand behind OrthoKinesis 100 percent," but privately the Clinic's Chief of Surgery, Peter Duquesne, told Waters, "You'd better get this straightened out quickly or we're going to have to drop you."

Questions

1) For many kinds of products, the federal government does not require pre-production design approval. Instead, consumers are expected to judge the risks themselves (based in many cases on information provided by the manufacturer). The threat of lawsuits disciplines companies not to produce dangerous products.

But in the case of medical devices, the law requires approval by the FDA before a device can be produced.

a) What are the reasons for requiring this? What kinds of products do you think pre-production approval should be required for?

b) Now, what are the disadvantages to society of requiring pre-production approval? (Hint: Don't just think about the OrthoKinesis story.) Are there ways that we could strengthen the consumer judgment/litigation system so that pre-production approval would be unneeded?

2) What, if anything, did OrthoKinesis do wrong? Think about:

a) The design process for Flexi II

b) The reaction by Blaylock and Lomax to the initial evidence of problems with the Flexi II, and to the 1991 initiation of the FDA investigation.

c) The actions Waters took when he took over as CEO in 1992.

5) In 1990, Santiago knew that top management was covering up possible defects in the Flexi II. However, he chose not to inform the FDA, and even agreed not to tell other managers such as Reardon. Was he obligated to tell? Why or why not? What would you have done in his place?

6) As of the end of 1994, Waters and his management team must make a number of decisions. They include:

* Fight the FDA charges, or seek a settlement?

* Decide on any statements to make to the public or to surgeons, the company's customer base.

* Make any additional changes in the company to prevent a repetition of these problems.

What course of action would you recommend for each?

COMCORE--Spring 1995 Prof. Chris Tilly

ORTHOKINESIS CASE

CASE UPDATE 2: "FETAL PROTECTION IN THE FACTORY"

February 28, 1995

Jim McCord, the VP for Human Resources at OrthoKinesis, had a problem on his hands. There was an opening in casting. Two production workers from inside the plant, Patty Soares and Betsaida Espin, both applied for the job, hoping to get the $1.50-an-hour raise that would come with the promotion. Both were qualified in terms of skills. But the casting job includes cleaning out machines with a variety of organic solvents, which can cause birth defects. Since Soares and Espin were aged 38 and 45, respectively, McCord feared that they might get pregnant, running the risk of birth defects and a big lawsuit against the company. (Note: The organic solvents can also cause chromosome damage in men, also potentially leading to birth defects.)

Rather than turn the women down flat, McCord explained his dilemma to each of them. "If you are willing to get yourself sterilized," he concluded, "then you can be a candidate for the job. Otherwise, it's too big a risk for you and any kids you might have." Not surprisingly, both women declined sterilization. Both said they didn't plan to get pregnant (Soares already had three children, and Espin was divorced and not seeing anybody), and both were still interested in the job. But McCord hired a man from outside the plant.

But now Soares and Espin are grumbling, and talking about filing a discrimination suit against the company. The HR chief at another company told McCord he'd better take a look at the Johnson Controls case, and McCord discovered that the Supreme Court had ruled against Johnson Controls in a very similar case!

1) Given that organic solvents can cause defects via either the father or the mother, why do you suppose the company barred women from the casting job while allowing men to do it?

2) Should OrthoKinesis be allowed to bar women from this job? Why or why not?

3) Some people have suggested that if companies are compelled to offer fertile women jobs that may cause birth defects, then the states should limit the companies' liability for such birth defects. Do you agree or disagree? Why?

4) Another view is that the company should be responsible for cleaning up the workplace so it is free of reproductive hazards. What are the arguments for and against this approach?

ORTHOKINESIS CASE
CASE UPDATE 3: "TO CONSORT OR NOT TO CONSORT?"

To read for April 3

> Like the previous updates, this is just for discussion in class. You are not expected to turn in a written assignment.

Cheryl Doucette felt like she was in over her head. Cheryl was the new Director of Regulatory Affairs for OrthoKinesis, hired as a result of a recommendation by the COMCORE Consulting Group. She had an undergraduate degree in biomedical engineering, a law degree, and years of experience working in the regulatory affairs office of a pharmaceutical company. Even so, she didn't feel prepared for all the tasks OrthoKinesis was handing her. At the large drug company, Doucette had been part of a larger office. Her job was narrow and well-defined: deal with the U.S. Food and Drug Administration and any state counterparts. But here at OrthoKinesis, a much smaller company, management seemed to be handing her just about anything that required dealing with government agencies. The company's counsel handled routine matters, such as contracts and litigation, but anything out of the ordinary ended up on her desk. This motley assortment of tasks came on top of handling ongoing communications with the FDA over problems with the Flexi II elbow, and paving the way for FDA approval of new hip and knee joint products.

The latest request came from the office of the U.S. National Institutes of Health (NIH). It was an invitation to join a public-private R&D consortium to develop new biomechanical products.

An invitation to join a...what?

Some background: In other countries, government often pulls together groups of companies--R&D consortia--to work on developing new products, usually with government assistance. In Japan, much R&D and new product development takes this form. In Europe, the highly successful Airbus passenger jet was developed by cooperation among several European governments and companies.

In the United States, there were some examples of this in the past, but in recent decades the government has done relatively little to encourage this kind of cooperation--in fact, the Justice Department generally views R&D consortia as a violation of antitrust laws.

But in 1984, the federal government passed a law that empowers the Commerce Department to authorize consortia in industries that are threatened by foreign competition. The first such consortium was SEMATECH, established in 1984. SEMATECH's goal was to develop the next generation of computer chip. It was funded for ten years with $100 million from semiconductor (computer chip) companies and $100 million from the federal government (mainly the Defense Department); in 1994 the funding was extended for another ten years. SEMATECH got mixed reviews. It did not make a breakthrough to the next generation of chips, but did make some other important innovations. Many observers felt that the companies sent second-rate engineers to work at SEMATECH, keeping the best thinkers to themselves. The small semiconductor companies felt that the big companies hijacked SEMATECH for their own purposes. People concerned about U.S. competitiveness worried that too many of SEMATECH's resources were going to military applications with little commercial potential (for example, SEMATECH developed gallium arsenide chips that could withstand nuclear radiation).

Also, most of the big companies have joint ventures with Japanese and German rivals such as Hitachi and Siemens, and do much of their production overseas. So many wondered whether the innovations developed at SEMATECH were really helping to create jobs in the United States.

Subsequent to SEMATECH, a number of other consortia got started, including one to develop high definition TV, and the Supercar Initiative to develop highly fuel-efficient vehicles. The Clinton administration has made new technology a centerpiece of its economic development strategy, and has tried to encourage industries and government agencies to form public-private consortia.

The New Prostheses Project was the latest of these initiatives. The goal was to create a leap forward in the quality and affordability of a variety of prostheses--artificial limbs, joints, and other body parts. For artificial joints, the main goals were to extend product lifetime and dramatically reduce production costs. The strategy was to pull together prosthesis manufacturers, advanced materials manufacturers, and researchers based at the National Institutes of Health (NIH) and at universities and medical schools around the country.

When Doucette got the information from the NIH, she presented it at a meeting of the management team. "So what's the deal?" Charles Waters asked.

"Well, if we buy in, they're willing to help us out with a bunch of things." She passed out copies of a memo that stated:

"Participating companies will be eligible for:

- Submitting proposals for NIH funding of research on prosthetic advances
- Privileged access to the New Prostheses Project Library, which will gather the world's preeminent collection of existing and new research on prostheses and prosthesis manufacturing. The Library will be housed in Bethesda, Maryland; abstracts will be available on-line or on CD-ROM; participants can borrow or purchase copies of research materials. The Library will only become open to the public after seven years.
- Access to a Technical Help service. The technicians staffing this service will tap a nationwide network of experts.
- Sharing in many of the advances attained throughout the project, without licensing fees
- Assistance in locating vendors who can provide new materials, parts, and processes
- Assistance with patenting, regulatory approvals, and specifically with the FDA approval process
- Assistance with marketing, especially overseas"

"So what's the catch?" persisted Waters. "There's got to be a catch."

"They want several things from us," Doucette replied. "First, $10,000 a year for five years--the amount varies by the size of the company, but we'd be paying $10,000. Potentially we could get that much and more back if we won grants.

"Second, they want us to send an engineer to Bethesda one week a year for five years to take part in symposia. Plus, we have to designate at least one expert--probably an engineer--who would be on call through the Technical Help service.

"Third, any technical advances we came up with would be the property of the consortium, not our exclusive property.

"And fourth, the flip side of that is that a committee decides whether some of the advances should be limited to a smaller number of companies. If so, they auction off ownership of the patents to the highest bidder, which can be a single company or a joint venture."

Rocco Gargiulo, the VP of R&D, who had remained silent up to this point, finally stirred. "Who's on the committee?" he asked.

"The majority are representatives of federal agencies--NIH, Commerce, Health and Human Services--and then there are industry representatives."

"Big government," snorted Marketing Manager Alice Reardon. "You bring in somebody to specialize in big government, and she just gets us more and more tangled up in it." Reardon made no secret of the fact that she had opposed hiring a Director of Regulatory Affairs; she thought regulatory issues could best be handled with the pre-existing management team.

"Plus, this is a Clinton scheme," noted National Marketing Manager Buddy Gooden--it was a rare occasion when he actually agreed with Reardon. "That means first of all, the plug probably gets pulled on this project in 1997 once there's a new president--it'll never last the five years it's supposed to. And besides, if we get on board with this, and especially if we lobby for extending it, we're not going to make any friends among the Republicans."

"Anyway," chimed in Zelda Goldstein, "this is chump change compared to the kinds of benefits the Republicans are giving us through the Contract with America. When litigation reform passed," the CFO continued, "our stock price jumped by 50 percent! They may have saved our necks."

"Now hold on a minute." Manufacturing VP Ricardo Santiago put his two cents in. "I thought we were in the business of making better products, not dodging litigation. What's so crazy about working with other companies and researchers to come up with a better product?"

"Yeah, relax, you guys," agreed Jim McCord, the HR director. "You're so accustomed to getting tied in knots by the federal government that you don't recognize a free lunch when you see one."

Reardon snorted again: "Free lunch! There's no such thing as a free lunch, at least not for us. I bet the big prosthesis companies wrote up this program for NIH. They'll get their piece of the pie, and we won't get any. Now that the Republicans are getting serious about dismantling big government, this is just a way to try and sneak it in through the back door. If you call that free lunch--"

"People, people," Waters interrupted. "We can't spend all day on this. Cheryl, I think you've heard the arguments pro and con. Why don't you have a memo on my desk in a day or two summarizing both sides and making a recommendation?"

Now Doucette was staring at her computer screen, and her head was spinning. She decided that to write a good memo, she had to go back to first principles: What does the government get from organizing an R&D consortium, and what does it have to give up? What does business get, and what does it give up? OK, she said to herself, this is starting to make sense.

QUESTIONS

1) Presumably, the government is getting involved in the R&D process because there are problems that make it difficult for individual companies to do it. What makes the development of a new technology difficult for individual businesses--especially a small company like OrthoKinesis?

2) In the discussion of environmental policies, we saw a lot of situations where an external cost provides a justification for government intervention. Here, instead, there is an external benefit that calls for government action. Explain. (Hint: What does the market not doing enough of in the absence of government prodding, and why?

3) The NIH is trying to help all companies in the prosthesis industry, not just one or a few. Why? Are there some situations where helping a single company makes sense?

4) The NIH has decided that most innovations will get shared by all participating companies, but a few will get auctioned off. What do you suppose is the rationale for these two aspects of the program? Do you agree with this approach, or would you push for different rules about who gets to exploit the innovations?

5) In what ways does this federal policy promote the New Competition, as Michael Best describes it? In what ways does it fall short of promoting the New Competition?

6) The federal government must choose what particular industries to support, and what technologies to develop. How should it choose?

7) Should the company take part in this program? Explain your reasoning, based on the pros and cons in the update or other considerations.

8) Should the government continue this kind of program? Again, explain your reasoning based on pros and cons. Can you suggest ways to improve this program that would give better results for the businesses involved, for society, or for both?

CASE UPDATE 4: A U.S.-JAPAN TRADE WAR

It is early 1994, and the U.S. and Japan are going head-to-head on trade, and OrthoKinesis is part of the issue. A "trade summit" to discuss new trade guidelines in autos, auto parts, insurance, medical equipment (including artificial joints), and telecommunications has failed to produce an agreement. Now trade negotiators on both sides are talking tough.

The U.S. is concerned because its trade deficit with Japan hit a record $59 billion in 1993. U.S. spokespeople claim that Japan is selling too much to the U.S., and buying too little from U.S. companies. In the past, U.S. industry representatives have accused Japanese companies of "dumping" goods such as steel and semiconductors in the U.S. (selling them below cost in order to boost market share). U.S. electronics and auto companies are currently considering bringing anti-dumping charges against Japanese businesses, though they have not yet moved on this.

But the main issue is U.S. companies' access to the Japanese home market. For example, Japan's government promised to buy 20% of its semiconductors abroad, but only hit that target once in 1992, and not since. They promised to open their markets to Motorola cellular phones, but then failed to make frequencies available in the Tokyo area, the main cellular phone market. One analyst says that Motorola has lost a two-year technology advantage because of the delay. The top U.S. trade negotiator, Special Trade Representative Mickey Kantor, has threatened to apply $300 million in tariffs to retaliate for the Motorola exclusion alone.

VP for Marketing Alice Reardon contacted Kantor's staff last fall because OrthoKinesis was facing similar obstacles. She found that many top Japanese surgeons wish to buy OK's elbows. But the hospital administrations, which depend on government reimbursement (Japan has a government-controlled national health plan), have refused to purchase these elbows, claiming to cite quality concerns. Instead, they are buying from Japanese prosthesis manufacturers. Only a few small hospitals have bought Orthokinesis joints. There is no "smoking gun" that proves this is a deliberate government policy, but in Reardon's view the pattern is clear. Kantor agreed, and the OrthoKinesis case has been added to the list of U.S. demands.

Will there be a trade war? Some observers think that's unlikely, because U.S. and Japanese companies themselves have close relationships. Motorola and its Japanese cellular phone rival, IDO, have a cordial buyer-seller relationship despite the dispute. Texas Instruments and Hitachi are jointly developing the next generation of memory chips. Even OrthoKinesis has a joint venture with Japanese medical giant Sansei, to build a factory in Hong Kong to supply the expanding Chinese market. For that matter, many Japanese companies are closely linked to the U.S. economy. White House trade negotiators considered limiting U.S.-based Japanese auto-makers' ability to import parts duty-free, but then dropped the idea when they realized it would cost jobs in the Southern communities that have set up these duty-free zones.

Questions

1) The U.S. is buying $59 billion per year more from Japan than it is selling to Japan. This means the Japanese have an extra $59 billion in U.S. dollars at the end of each year, and nowhere to spend it. Why do they keep taking these dollars?

2) Japan is restricting U.S. access to some of its markets. Why? Don't they know about the advantages of free trade?

3) Now the U.S. government is considering its own additional trade restrictions. Why? Don't they see the advantages of free trade? Also, why would they do this and set up NAFTA at the same time?

4) What's so bad about a trade war, anyway? Who gets hurt? (And who benefits?)

5) What do you think Robert Reich might recommend as U.S. policy in this trade dispute, and why?

6) In past trade disputes, Japan has retaliated against the U.S. by saying, "You say our companies are selling you too much? OK, we'll sell you less." For example, in one case Japan limited the amount of computer memory chips that the U.S. could buy. Why is this a "punishment" for the U.S.?

CASE UPDATE 5: HIGH TIME FOR DRUG TESTING?
April 18

Orthokinesis VP for Manufacturing Ricardo Santiago stormed into the office of Jim McCord, VP for Human Resources. "Twenty-five percent of the joint stems were scrap last month!" he exclaimed.

"Calm down, Ricardo," responded McCord. "I agree, you got a problem. But what do you want me to do about it?"

"Simple: drug testing," Santiago retorted.

"Drug testing?" echoed McCord. "What makes you think it's drugs?"

"The highest scrap rate is on the evening shift. They're a bunch of young guys, not much supervision...."

"Well," said McCord, "we've never done drug tests before. If we want to get into drug testing, we can't just do it when we feel like it. We need a uniform policy."

Santiago paced back and forth. (McCord was starting to wonder if he was on drugs. Maybe it was just too much coffee.) "I'm not talking about just testing the evening shift. We should be testing everybody in the manufacturing end of the business."

It went against all of McCord's instincts. "But what about their right to privacy? This will totally destroy any relationship of trust between employees and management. Besides, the good tests are expensive."

"Privacy? Trust? Expensive?" exploded Santiago. "What about the customers' rights to a joint that works? What about the scrap costs that I'm eating right now? Besides, didn't Reagan make it a federal law for employers to prevent drug abuse?"

"The Drug Free Workplace Act of 1988," agreed McCord. "But that still doesn't mean we can--or should--test whoever we feel like. Like I said, we need to design a policy."

Questions

1) What are the main arguments in favor of drug testing--from the viewpoint of the company? The workers? Consumers? Society?

2) What are the main arguments against drug testing, from the same viewpoints?

3) What do you think would be conservative, liberal, and radical views of the issue of drug testing?

4) Help McCord design a drug testing policy. Who should be subject to tests? How should the tests be conducted? What should be the response to a positive test? How should drug testing be linked to a broader company policy against drug abuse? (You may wish to refer to the readings.)

COMCORE--Spring 1995 Prof. Chris Tilly

CASE UPDATE 6: AFFIRMATIVE INACTION?

May 2, 1995

First came the memo:

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MEMORANDUM

TO: Charles Waters, CEO
FROM: Jim McCord, Human Resources
RE: Proposal to modify company's affirmative action policy
DATE: April 24, 1995

I am writing to propose that we adopt a stronger affirmative action policy. This may seem odd, given that politically the tide is running the other way right now. But let me first offer a rationale for moving in this direction, and then sketch some elements of a stronger policy.

Rationale

1) Our current AA/EEO policy is vague, on the whole. It starts by clearly stating that we will not discriminate, and then goes on to state that we will take active steps to ensure equal employment opportunity. But it never specifies these active steps. In practice, few active steps are taken.

2) Stronger affirmative action is the right thing to do. As the federal Glass Ceilings Report released last month stated, there is still discrimination against blacks, Hispanics, and women, even though companies have almost universally adopted vaguely worded affirmative action policies like ours. At our company, these groups are underrepresented at all but the lowest levels of employment, despite some very visible exceptions. This is particularly a problem in manufacturing and sales: although the top people in these areas are a Hispanic and a woman, none of the lower level managers or supervisors are minorities or women.

3) Stronger affirmative action remains the law of the land, at least for now. The Executive Orders that make up federal and state affirmative action policy mandate goals, a plan for achieving those goals, and a timetable to benchmark our progress against. Our current policy does not include any of this. Upcoming changes in the law may weaken this legal mandate somewhat; they are unlikely to invalidate the type of stronger policy I propose.

4) Without stronger affirmative action, we are vulnerable to litigation. The situation with Soares and Espin seeking jobs in casting [see Case Update 2] was a wakeup call. Again, we are vulnerable in sales and manufacturing. Colonel Blaylock's years of "old boy network" hiring left their mark, and a small number of visible hires (Santiago, Reardon) do not eliminate the issue.

5) Stronger affirmative action can also help us achieve a happier, more productive workforce. In manufacturing, for example, a large part of the workforce is Hispanic and Portuguese or Cape Verdean women, who currently see little prospect for promotion. Creating

opportunities for promotion could win us a great deal of good will--and wouldn't hurt with the community, either.

Policy changes

I would recommend the following four policy changes:

a) Create a formal in-house management training program, and encourage women and minorities to apply. Currently, most managers beyond the front-line supervisor or crew leader are hired from outside the company.

b) Extend tuition reimbursement benefits to all employees in the company, not just white collar workers. If someone in manufacturing wants to get a BS in management, or even an MBA, more power to them! (Tuition reimbursement would still only apply to skills relevant to the company.)

c) Broaden our recruiting networks. We should establish connections with black and Hispanic student associations at the colleges and community colleges where we recruit, make connections with minority and women's associations of small businesses, engineers, etc.

d) Consider race, ethnicity, and gender as one among many qualifications for upper level jobs. This does not mean quotas, and does not mean hiring unqualified people--all hires must still meet the relevant qualifications. It does mean that affirmative action could tip the balance to groups that are currently underrepresented. It makes sense that when hiring somebody to supervise a workforce of Hispanic and Portuguese women, a Hispanic or Portuguese woman would have added qualifications. It makes sense that in selling to a diverse world, one consideration for a hire to the sales force is whether the person will contribute to diversity in our ranks.

I look forward to your response to these suggestions. I'd be happy to work out a more detailed plan for implementation.

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Several days after the memo, Waters called McCord into his office. McCord could tell Waters wasn't pleased, because he started by praising his human resource chief: "You're sharp, you're dedicated, you're creative."

"'But...'" replied McCord. "I know you're about to get to the 'but'."

"But you're a bit of a dreamer. I mean, why now? Our affirmative action plan has worked just fine for years. And now, when the laws are probably about to get changed, you seem determined to move in exactly the opposite direction from the President and Congress. Why, Jim?"

McCord smiled. "I guess seeing the guns getting rolled out to attack affirmative action made me think harder about what we could and should be doing. Plus, the situation with Soares and Espin was a scare--that got me thinking."

"I don't suppose the fact that you're black has anything to do with this?" Waters asked bluntly.

"Of course it does," said McCord. "Damn it, Chuck, the job I held before this one, I beat a white guy out for a promotion. He went around saying I got the promotion because I was black. But I had more experience, my degree was from a better school, my work record was at least as good--it was just sour grapes on his part. But a lot of people believed him!"

But as McCord finished this statement, he realized he had made a tactical error by bringing his personal experience into the discussion. Waters had an "I've-made-up-my-mind" tone in his voice as he responded: "Look, I know it's hard for a black man in the business world. But I don't want to see your ideals or your grudges driving company policy. This company is not going to be a guinea pig."

"The things I'm talking about, plenty of other companies do," McCord interjected.

"That's fine, but we're going to keep a low profile on this issue," said Waters. "Our profile is plenty high already because of the Flexi II. So when it comes to affirmative action, we need to stick to the basics: we will not discriminate, we will try to give an equal chance to everybody. I think you'll agree that we've treated you fairly and equally.

"But policies like the ones you're suggesting can make us a target from the other side," Waters continued. "We could get hit by a reverse discrimination lawsuit--especially with your last recommendation--it's basically calling for adopting race and gender preferences. That could easily be against the law a year from now, the way Congress is moving. And it may make us popular with the Puerto Rican women, but it's not going to win us any points with the white males--and I can see their point of view. Blaylock may have had his own Southern style of picking managers, but why should these guys have to pay for his sins? Besides, if a woman gets promoted to manager through a special training program, everybody including her is going to wonder if she just got the job because she's a woman. And Jim, I can't see how the company can justify hiring anybody except the most qualified person."

"My bottom line," Waters concluded, "is that we've got to stick with our current affirmative action policy."

QUESTIONS

1) Most of Waters's response is posed in pragmatic terms, but he also makes some normative ("what's right") statements, including some that match up with the views of William Bradford Reynolds (see readings). What are the normative statements?

2) Assess the merits of the two men's arguments.

3) Do you think the best affirmative action policy for OrthoKinesis would be: (i) "as is" (as Waters argues), (ii) adopting McCord's changes, or (iii) a different set of changes (perhaps

incorporating some of McCord's suggestions--if you choose this option, try to spell out the changes). Defend your choice.

COMCORE B--Spring 1995 Prof. Chris Tilly

ORTHOKINESIS CASE
CASE UPDATE 7: "FAMILY MATTERS"

May 8, 1995

As OrthoKinesis and other companies experiment with more "family-friendly" employment practices, they sometimes run into unexpected problems. Consider the following 3 scenarios (based on real-life events). Note that at OrthoKinesis, the majority of the lower level production workforce and almost all of the clerical workforce are female, but most managers, engineers and most of the sales force are men.

For each one, discuss how you would handle the situation. Since the information in the descriptions is limited, figure out what else your decision would depend on.

1) You are Alice Reardon, VP for Marketing. Two full-time, productive sales representatives, both women, have children around the same time. Both request reduced hours, saying that otherwise they may have to leave. In order to keep them, you work out a job-share in which they split a 40 hour week.

The arrangement appears to be going well. But then some of the company's best customers complain that they now have to deal with two people from your department. "I want somebody I can depend on, instead of worrying about who will answer my call today," one purchaser for a major hospital chain comments.

2) You are Ricardo Santiago, VP for manufacturing. As a special arrangement, you allow an employee with young children to work a compressed work week (4 10-hour days) and take school holidays off. But then a childless co-worker of this employee appears in your office and demands an unpaid day off, even though she has used up all of her vacation and personal time. "If you're going to give her that flexibility, why not me?" she asks.

3) Finally, you are Charles Waters, the company's CEO. You pride yourself as being a little "ahead of the curve" in human resource issues. You offer up to 12 weeks a year of unpaid family leave for childbirth or illness in the family. The Family Leave Act before Congress would require companies to offer what you're already offering (up to 12 weeks unpaid leave).

Another CEO you're friendly with calls up. "We're getting together an effort to lobby Congress against the Family Leave Act," he says. "Maybe you're big enough to afford that kind of benefit, but it's going to hurt a lot of smaller companies. Besides, if the law passes you'll be locked into it. Will you join us in opposing the law?"

(The Family Leave Act was passed in 1992, and went into effect in August of 1993. However, there has been some difficulty in implementing it--many companies have refused to grant leaves either due to ignorance of the law or simple reluctance to abide by it.)

APPENDIX F

ORTHOKINESIS, INC.

Deliverables for COMCORE B

COMCORE
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October 6, 1994

First Deliverable Assignment

The first deliverable is designed to develop an understanding of the characteristics of the new product and its manufacturing requirements. You will also develop an understanding of the financial requirements imposed by this new product, and the firm's capacity to undertake this project.

Section I.

General Business Considerations

1) Describe your product in its core dimension as distinguished from its tangible dimension.

2) Describe the probable market for your product in as much detail as possible. Do not confine your description to the USA.

- Who is your customer?
- How is this product bought? When? Where?
- Estimate market potential;
- Describe the nature of competition in this market.

There will be some vagueness and ambiguity at this stage. However, where you lack details, indicate what is missing, where the information is located, and how you would get it. The principal marketing challenge at this stage is to investigate the viability of the market and to communicate this viability to your bosses.

5) **Industry and Company analysis:** Perform ratio analysis to compare the performance of your company to the industry.

6) **Pro-Forma Statements:** Prepare a pro forma balance sheet and income statement for the next five years.

7) How will capital requirements for the project affect the future flexibility of the company? Conduct detailed financial analysis based on costs associated with prototypes and information generated from customer feedback. Evaluate any alternate manufacturing processes and value of product features. What items constitute cost drivers?

Section II.

Design Feasibility/ Manufacturing Considerations

1) Describe your products in their tangible dimensions. What issues should you consider during production of prototypes, part lists, and potential suppliers. Describe how you

would conduct a value analysis to relate the cost of each feature to the value provided by the feature to the customers. For the dimensions identified, which have the tightest specification limits?

2) Identify the manufacturing equipment necessary to produce these products. What is the quality assurance plan (sampling procedures and test methods used to ascertain quality)? How would you measure the various attributes of quality?

3) Develop specific customer requirements, design requirements, and product specifications for your product. (You may have to take the role of the customer, and design engineer to come up with target values). You may find an abbreviated QFD analysis helpful in this area.

4) How would you evaluate suppliers? Identify specific potential suppliers (SIC codes may be helpful in this area). Discuss the information you would use for this purpose, its quality, and the steps you would take to ensure adequate information quality.

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November 7, 1994

Second Deliverable Assignment

You have received approval to proceed further with your product development plan. While the product concept has been approved, at this stage you need to develop an understanding of several issues. Now the product must be developed and introduced in the market. You have to make sure that technical, commercial, manufacturing, human, and financial resources needed to accomplish this are available in the company. Therefore, you need to understand the market, the value-chain process in this market, and the manufacturing process. You also need to understand the financial viability of the new product and associated risks, that is, the consequences for the firm if forecasts are not realized as actual sales, or if introduction of the new product is delayed. These issues can be addressed if you pay attention to the items and questions identified below.

Please refer to the schedule that was given to you at the beginning of the semester for due dates. Remember, you should not answer each question separately. Instead, you should prepare a cohesive report. Your executive summary should address the broad issues raised in the previous paragraph. Please provide five copies of your report. Do not use any covers, but use a staple on the upper left hand corner.

General Business Considerations

1) Identify and justify an overseas market for the OrthoKinesis product line (not Canada).
2) Present your marketing plan for this market in complete detail. This should include at least the following considerations:
    a) Recommend and justify a mode of entry into this market;
    b) identify mandatory product adaptations;
    c) identify discretionary product adaptations;
    d) describe your communication strategy;
    e) describe your promotional strategy;
    f) describe your pricing strategy; include the possibility of learning curve pricing.
3) Sales forecast based on your marketing plan, supplemented by information supplied in class.
4) Develop a broad value chain structure for the prosthesis manufacturing industry, that is, from basic raw materials through the ultimate end-use-product delivery into the final consumers' hands.
5) Specifically identify and provide work flow diagrams of the processes involved in manufacturing.
6) Can capital be raised to implement the project? At what cost
7) Risk Review: Are there any unknowns or uncertain areas which can have adverse or favorable impact on the product program? These include items such as a pending

legislative action, industry deliberations on changes in standards, tests for which results are not available at the present time, additional information needed from further prototype testing, and other considerations of similar nature that affect the product program either favorable or unfavorable.

8) Due to the market potential of your product, many competitors are expected to move into this business by the beginning of the second year. These competitive pressures will force you to drop selling price by 30% in the second year; 10% in the third year, and 5% in the fourth year. Prices are expected to stabilize after that. What is the impact of these anticipated changes on your decision?

9) How sensitive is your valuation of the new product to a decrease in sales volume? That is, if you delay the decision to enter this market by one year, what are its implications? The information provided under item 11 above will be helpful in evaluation this question.

Design Feasibility/ Manufacturing Considerations

1) Develop a facility layout for elbow production and your new product. Keep in mind capacity requirements based on your sales forecast for each product.

2) Evaluate recommendations for manufacturing technology enhancement (CAD, CAM, CIM, Flexible Cells, etc.) for your product line. Which option(s) would you recommend?

3) Develop an aggregate production plan for elbow and new product manufacturing for the coming year. Develop your plan on a monthly basis, indicate the number of units to be produced and changes that would be necessary (subcontract, hire/fire workers, etc.).

4) Describe how you could use Deming's 14 principles as a guide to run the manufacturing function consistent with a total quality environment.

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January 24, 1995

Third Deliverable Assignment

OrthoKinesis has attracted a large market for its joint products. Its success in foreign markets has also attracted a large number of competitors. As a result OrthoKinesis is facing intense competition in all markets. Over the years, even though you have been able to increase the quantity shipped, you had to reduce prices to gain volume. This has helped you to get established as a major competitor in this market. Your competitors are putting further pressure on your margins by forcing you to continue to reduce prices. You now need to develop strategies that will help you grow your business in this changed environment. Because you have a complete line-up of implant products, and because you are one of the stronger competitors in this business, expanding into additional overseas markets presents a viable strategy.

Please refer to the schedule that was given to you at the beginning of the semester for due dates. Remember, you should not answer each question separately. Instead, you should prepare a cohesive report. Your executive summary should address the broad issues raised in the previous paragraph. Please provide five copies of your report. Do not use any covers, but use a staple on the upper left hand corner. Prepare your report using the format prescribed for COMCORE.

General Management Issues

As reported in the Case Update, OrthoKinesis ran into trouble because it failed to report safety problems with one of its product lines to the Food and Drug Administration (FDA). As a result, the FDA fined the company, and the company may also be liable to lawsuits from patients as well.

There are a variety of possible approaches to **preventing** this kind of problem in the future. Three possibilities are:

- A stronger social responsibility stance within the company.
- Stronger regulatory pressure from the FDA.
- A change in corporate governance, representing groups that are not currently represented.

These three approaches differ markedly. Your assignment is as follows:

1) Choose one of the three viewpoints about business and society, that is, conservative, liberal, or radical. State which one you have chosen.

2) Based on this viewpoint, say which of the three approaches to preventing future safety problems you like best. Explain why you like this approach, and what you don't like about the other two approaches. (You are not speaking from the viewpoint of the company, but as an outside observer with a particular viewpoint.)

3) Sketch out how you would carry out the approach. Be concrete: what steps would need to be taken and by whom.

Failure to comply with various requirements faced by a company is the result of leadership style used by its managers. The approach used by the management also affects the company's overall productivity.

1) Analyze how the leadership impacts the productivity of the company.
2) Propose and analyze an organization structure which will maximize productivity.

Cost Management Issues

Use the value chain framework you developed in Deliverable 2.

1) Begin to construct "The ABC Cross" by identifying the resource pools. Use the processes identified in your value chain as activities. Identify your objects of work and the activity drivers that will assign costs to the objects of work.
2) Establish a cost structure for OrthoKinesis. What seems to be the largest source of the cost of your product?
3) Develop a target cost based on a market price. In the next five years, what do you expect will have the greatest effect on the price OrthoKinesis can charge? Will this effect increase or decrease OrthoKinesis' ability to earn an adequate profit? Explain.
4) What do you plan to do about any problems associated with (2) and (3)?

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April 10, 1995

Fourth Deliverable Assignment

Growth of OrthoKinesis has not been entirely without problems. Problems with regulators have increased the pressure for focusing on issues that go beyond product design and manufacturing considerations. A great deal of effort in the past has been spent on providing high value-added products to OrthoKinesis' customers. This was necessary to get established in the marketplace. In the future, however, growth will depend on creating a positive image of the company in the minds of its stakeholders. This will require that OrthoKinesis not only continue to serve its customers by providing a high value-added product, but also focus on concerns of regulators, employees, and other constituents. This deliverable, therefore, requires you to take a strategic view of the business.

Please refer to the schedule that was given to you at the beginning of the semester for due dates. Remember, you should not answer each question separately. Instead, you should prepare a cohesive report. Your executive summary should address the broad issues raised in the previous paragraph. Please provide five copies of your report. Do not use any covers, but use a staple on the upper left hand corner. Prepare your report using the format prescribed for COMCORE.

General Management Issues

Develop a set of social responsibility guidelines for OrthoKinesis. The guidelines should cover four areas:

1) General guidelines,
2) Consumer rights and safety,
3) Environmental issues, and
4) The company workforce.

In each area, the guidelines should include:

a) Principles, and
b) Action steps for years 1, 2, and 3.

In Deliverable 3, you have already done some of this work for category 2, that is, consumer rights and safety. Incorporate this work into the set of guidelines you prepare for this deliverable.

As you lay these out, be careful to distinguish among at least three different rationales for the guidelines:

i) Things that are required by law,
ii) Things that meet other company objectives (such as winning repeat customers), and
iii) Things that the company should do because they are the right things to do.

Remember, you may be able to think of other rationales as well. Of course, many guidelines will satisfy two or more of these rationales. Nonetheless, be clear about the relevant rationale(s) behind each guideline or set of guidelines.

The document you produce should be an internal company document, not a public relations document. In other words, you should be worrying about how well the document can serve as a guide to action by actors within the company, not how it would look to the public.

Your sources should include:

1) Course readings.

2) Other publications, where relevant. You may wish to draw on social responsibility or ethics plans developed by other companies. (For example, General Dynamics developed a company-wide ethics plan after several scandals involving fraud in federal contracting.) However, keep in mind that anything you see from other companies is to some extent a public relations document.

3) At least two interviews, conducted by you—one with a representative from a manufacturing company, and one with a representative of a regulatory or advocacy group that works on consumer, environmental, or workforce issues, or general corporate social responsibility issues. Treat these interviews like other sources—weigh how much credibility you will give them, and draw on them throughout the assignment where relevant.

Be sure to list all sources at the end of the assignment. Whenever you mention a fact in the paper, cite the source for that fact. When you quote directly from an article or person, use quotation marks. Avoid using close paraphrases; it is better to simply quote instead. Do not hand in transcripts of the interviews. Instead, use these as source material to quote or cite from in the same way that you would use an article.

By its nature, this part of the assignment will generate lists of items. To enhance readability, develop a clear set of heads and subheads that conveys the outline of the document. Lists of bulleted items may be appropriate for parts of the document. Use narrative only when needed to explain or justify a point. Depending on how complicated the document turns out to be, you may also want to create a chart summarizing it.

Cost Management Issues

In every industry, several factors are important to long-term success. OrthoKinesis operates in the prosthesis industry. Integrate a discussion of:

1) the critical success factors for the prosthesis industry, and

2) specific performance measures to be tracked at OrthoKinesis to understand how it is performing with respect to these critical success factors.

What is the relationship of these items (1) and (2) to the activity-based costing (ABC) system? (Use your work from Deliverables 2 and 3.) Discuss processes/activities that will influence or be important to each of the measures you identified in (1) and (2) above. This represents the activity-based management portion of the ABC cross. This effort should help achieve continuous improvement. Complete your specific portion of the ABC cross to satisfy part of this requirement.

Discussion:

You must determine what it is that you are going to track to evaluate OrthoKinesis' performance in regard to a "balanced scorecard" (Robert S. Kaplan and David P. Norton, *The Balanced Scorecard—Measures That Drive Performance*, **Harvard Business Review**, January-February 1992, pp. 71 - 79.) which should also consider your industry's critical success factors. You will discuss the elements that are critical for success in this industry and develop and explain the measures that will track these factors. OrthoKinesis should set goals or benchmarks that focus on the short run (operational) and the long run (strategic) for the four Kaplan categories: (1) financial perspective, (2) customer perspective, (3) internal business perspective, and (4) innovation and learning perspective, plus a fifth element: (5) an environmental perspective. The following list provides some examples of possible performance measurement areas, but should not be considered required nor exhaustive.

Quality
Flexibility
Cycle time
Sales volume
Delivery
Productivity
Global readiness
Environmental issues
Customer Service
Responsiveness
Technological leadership
Price and cost leadership
Waste
Profitability
Overall

What kind of improvements are you seeking in your chosen areas of performance measurement? Do you feel it is realistic to expect to achieve continuous improvement in these areas? Why? Why not?

Management Issues

1) Articulate the company's strategic objectives for years 1, 2, and 3.

2) Present a plan to achieve the strategic objectives including milestones and person responsible for each activity.

APPENDIX G

Writing Style Guide for COMCORE

University of Massachusetts Lowell

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NOTES ON THE FORMAT OF A BUSINESS REPORT

Nearly all important business information is communicated in writing. (It might also be presented orally, but the written version is the one that counts.) What's more, today's professionals and middle managers are expected to do their own writing and word processing with little or no secretarial help. A well-organized and well-written report will carry the day. Its recommendations will be followed. Its author will be promoted. In other words, writing is crucial to your career. Like it or not, that is a fact of life. Ignore it only at your peril.

Much business writing consists of reports on subjects which you have studied and analyzed: the best production method for a particular product, a marketing plan for the product, NAFTA's impact on international sales. Such reports, if they are more than five or six pages long, use a standard format in most of American business. It suits COMCORE reports as well.

Report Components

Most reports have the following components. Specific details about these components are provided in the next section.

1. Cover Page
2. Table of Contents
3. Executive Summary
4. Introduction (or Statement of the Problem)
5. Background (optional)
6. Approach to Solution (optional)
7. Additional sections as required
8. Conclusions/Recommendations
9. Figures
10. Appendices

Specifics

This section explains each section of a business report in more detail. The recommendations apply to most reports you will write in school or in your first several years on the job.

Cover Page

This should give the title of the report, the name(s) of its author(s), his/her/their organization(s), and the date of the report. If it is a revision of an earlier report, say so: "November 9, 1993; revised November 23, 1993." Simple graphics are OK. Fancy graphics might make a reader think you put effort into pictures that you could have put into content.

Table of Contents

If a report is more than about three sections or about ten pages long, a table of contents will help readers find what they are looking for. It should be on a separate page immediately following the cover page. It should list each section and appendix with its page number. List subsections as well if some of your report's sections are more than five or six pages long.

The table of contents will usually not fill a page. Double-space it and move its top line down to balance the page layout. Don't squeeze it up to the top of the page.

Executive Summary

This section is usually called "Executive Summary" even though it's not just for executives. It summarizes the report so people can find out at a glance what's in the rest of the report and decide if it's worth their time to read it. It should state the problem briefly, identify what is in each section of the report, make any points that everyone who picks up the report should be aware of, and summarize your major conclusions.

Don't justify your conclusions in the Executive Summary. Just state them. Your readers can read the body of the report if they want the justification.

The Executive Summary should hardly ever be more than one page long. If yours starts to get longer, think about its primary purpose: to help people decide if they should read the whole report. If something isn't necessary for that specific purpose, take it out.

Introduction (or Statement of the Problem)

Here you state what problem you are trying to solve with your report. Start with a clear statement of what it is about: "This report makes and justifies recommendations for establishing a human colony on the seventh moon of Saturn." Explain why you have decided to answer this question, who (or what policy) dictated that it should be answered or another reason it is important, who has been working on the answer and for how long, and what they did.

After reading this section, readers should know what problem you were addressing and why that problem matters to them. They will not necessarily know how you addressed it or what you concluded.

This section should not normally exceed two or three pages.

Background (Optional)

If a reader requires more than a paragraph or two of background information to understand what you did and why you did it, use this section. If the necessary background is minimal, put it into the introduction. If you want to include detailed technical information, put it in an appendix.

Approach to Solution (Optional)

Use this section if your approach to the problem was at all unusual, might not be expected by your readers, or needs explanation. For example, if you carried out a market research survey, you can use this section to explain how you chose the survey subjects ("Every 10th adult leaving the Burlington Mall Athlete's Foot store on Saturday, Nov. 13, 1993") and why. Otherwise, skip it.

If this section is just a paragraph or so, put it in the introduction.

Other Sections as Required

The nature and number of these sections will depend on your report. Break your subject into three to ten logical areas. Don't use so many sections that they average under a page, though one or two short sections are OK.) Use an outline to make sure your sections cover all the necessary topics and follow a logical sequence.

You don't need transition sentences between sections. Don't end a section with "In the next section, we'll discuss finances." Anyone who turns the page and sees the heading "Finances" will figure this out. Just wrap up the section and move on.

Conclusions/Recommendations

You concluded something or recommended something, right? Put it here so people will see clearly what it is. Don't bury it in the rest of the report where it might be missed. If conclusions are scattered through the report, pull them together and repeat them here.

Figures

Most reports group figures at the end. This makes typing or word processing easier, as graphics don't have to be pasted (physically or electronically) into the body of the report. You can deal with the text of the report as a unit and then staple the figures onto the end.

If your word processor can put graphics in text, consider placing small figures in the report where they are referred to. This makes the report a bit easier to read—no need to flip back and forth to match up a picture with its discussion—and livens up its appearance a bit.

Appendices

Put all your detailed data here. Your report could refer to a break-even point of 714 units without justifying that number, saying only "See Appendix A for break-even calculations."

Appendices, like figures, may have been printed elsewhere—a spreadsheet, a memo initiating a study, an earlier report attached for background, market research data from a survey firm. This is, however, not a fixed rule. Many appendices are typed along with the body of the report. Put anything in an appendix if it makes the body of your report read more smoothly.

Formatting

Number every page in the body of your report. The Table of Contents is usually page 1.

Start a new page for every section. Don't start a new page for a subsection unless you're near the bottom of the previous page. Never have a subsection heading as the last line of a page, with the text of that subsection starting at the top of the next page.

Number each section, starting with the Executive Summary. While some people number sections as 1.0, 2.0, 3.0, etc., most readers find the .0s on the end a bit silly. Stick to 1, 2, 3.

Number subsections within each major section. Subsections of Section 2 are 2.1, 2.2, etc. Use third-level section numbers rarely, fourth-level almost never. The outline numbering style of I.A.1.a.i, which many people learn in high school, is hardly ever used in business.

Mechanics (grammar, spelling, word usage, sentence structure, etc.)

These must be absolutely, totally, impeccably perfect. There are no exceptions. None. Ever.

People who make important decisions are often quite literate and sensitive to the mechanics of standard written English. (Professors can be like that too.) No matter how much they try to concentrate on the content of your report, they will subconsciously think "How much can this person know? (S)he can't even spell!"

Check proper nouns carefully. Anyone who writes "Dunn and Bradstreet" might as well also write "I didn't pay attention to the D&B material." Even if it's a typo, it will damage your credibility in a situation where you can't see it happen and therefore have no chance to fix it.

If you have made it to your junior year at UMass Lowell you are no dummy. If you have trouble with the mechanics of English, you know it. Find someone to help you (such as The Write Place) and allow time to use their services.

Don't trust a spelling checker too much. Use it, but remember it can't catch everything. It can't catch "weather" for "whether," "there" for "their," "effect" for "affect," etc., or even typos such as "if" for "of." A spelling checker program is no substitute for proofreading.

Electronic grammar checkers, as of 1993, are not normally helpful. They are good for a few specific purposes, such as catching a tendency to lapse into passive voice ("The survey was done by us …") too often. They will not turn poor writing into good writing.

Pare your writing to get rid of all the fat. Don't add words to make your report longer: padding looks like padding. Also, don't use big words to impress your audience. They don't work—especially if, as often happens, you're not used to using them so you use them wrong. Say what must be said, and no more, in the simplest words that can do the job.

Printing

Most business reports today are produced on laser printers. Laser printers offer a choice of fonts (type faces), letter styles (italic, bold, etc.) and print sizes. Proper choices can make your report easier to read and will help you make a good impression. The following suggestions apply if you don't have a corporate standard to guide your choices.

Stick with serif fonts—fonts with little lines at the tops and bottoms of the letters, like this one—for large blocks of text. Fonts without serifs (called sans serif fonts) look clean, crisp and modern, but they're harder to read in large doses. Serifs help guide the eye along the line and reduce the subconscious mental effort of recognizing letter forms. Energy that the reader doesn't waste on recognizing letters is energy left over to appreciate your message.

Sans serif fonts are good for headings, figure captions, and tables.

Different systems offer different font choices. Experiment with yours to find one you like.

Use italics and boldface for emphasis, not underlining. Underlining is a substitute for italics. It's used in handwriting and on a typewriter where true italics aren't available. It generally doesn't look good in laser printing. If your printer has the real thing, use it.

Most systems produce 12-point type if you don't tell them to switch. Don't use anything bigger for the main text of your report. You can go a bit smaller (down to 10-point, no further) if you want to save paper. Also, some fonts are smaller than others for a given point size because of their letter designs. The font of this memo, which is in 12-point size, is an example. Most other fonts, if also printed in 12-point size, are bigger.

You can use larger sizes for headings. Don't go over 18-point except on the cover page.

Don't go wild with fonts, sizes, boldface, shading, borders, etc. Having a laser printer doesn't turn mere mortals into graphic designers. We just create distracting "visual clutter." Leave fancy stuff to the pros.